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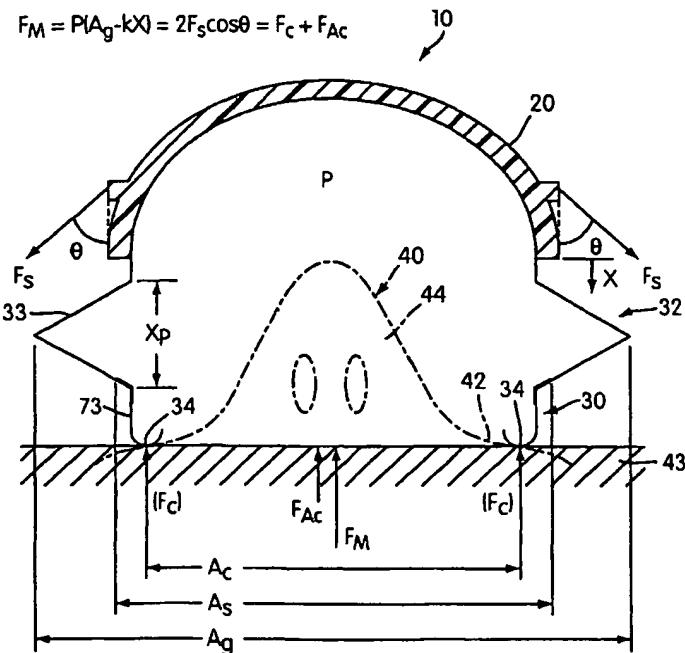
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(54) Title: MASK WITH GUSSET



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(57) Abstract: A mask system for delivering air to a user includes a suspension mechanism (32) to allow relative movement between a face-contacting cushion (30) and a mask shell (20). The suspension mechanism also provides a predetermined force to the cushion that is a function of mask pressure, displacement of the cushion or both.



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MASK WITH GUSSET

This invention relates generally to masks for use in respiratory therapy. One use is in CPAP treatment of Obstructive Sleep Apnea. However, the mask arrangements presented herein are useful in other types of respiratory therapy. In the quest for an improved mask arrangement for respiratory therapy, there are various design objectives – effectiveness of seal between the mask and the patient's face, good compliance with a prescribed therapy regime, and patient comfort. The present invention provides various embodiments of a novel mask arrangement, which offers 10 several distinct advantages over known mask arrangements.

BACKGROUND

In respiratory therapy where air is delivered to the mask under pressure, it is 15 important to maintain a good seal between the mask and the patient's face. Leaks between the mask and the patient's face can reduce the desired air pressure in the mask and create increased noise. Both can reduce the effectiveness of, and compliance with, the therapy. In the first instance, the prescribed treatment parameters are not being maintained. In the latter, the increased noise can disrupt the sleep cycle 20 of both the patient and the patient's bed partner.

Leaks are especially prone to occur as the patient moves during the night. Drag and movement of the air delivery tube or the mask system as the patient turns or moves can alter the positioning and alignment of the mask with respect to the patient's 25 face, which movement can be translated or transferred to the cushion seal, creating leaks. Thus, while the mask may initially be leak free when attached to the patient, leaks are prone to develop later in the night as the patient moves in bed, awakening the patient. Hence, patients may tighten straps more than is necessary for pressure requirements in order to reduce or prevent leaks that result from movement.

Many different mask systems are known. One broad group of known mask systems include a rigid shell, a face-contacting cushion and headgear. The shell typically encompasses the nose or nose and mouth. Some known shells encompass the entire face. The cushion is typically constructed from a soft material such as silicone.

5 A headgear provides a means to secure the mask in position. One known form of headgear consists of an arrangement of straps.

Certain mask designs have been developed to increase the flexibility of the mask cushion to enhance patient comfort while maintaining an effective seal between 10 the mask and the patient. The Bubble Cushion (a registered trademark of ResMed, Ltd.) Mask, covered by US Patent No. 5,243,971, the subject matter of which is incorporated herein by reference, uses a flexible cushion membrane attached to a mask shell and the pressure inside the mask system to assist in the seal of the cushion membrane itself against the skin or face of the user.

15 The ResMed Mirage (a registered trademark of ResMed, Ltd.) Mask System, is covered by, inter alia, US Patent No. 6,112,746, the subject matter of which is incorporated herein by reference, has a contoured, three-dimensionally shaped cushion having an outer face-contacting membrane spaced apart from an inner frame rim to 20 both assist in the seal and increase the comfort of the patient. Neither of these masks incorporates an expanded gusset section for mounting the cushion to the mask to assist in sealing the mask to the patient (user).

A known fitting procedure with a known mask has been to supply the 25 maximum air pressure to the mask that will be supplied to the mask during the therapy and to adjust the strap tension to the necessary level to prevent leaks at that maximum air pressure. However, in many therapy regimens, this maximum air pressure is often encountered only during a portion of the duration of the therapy and the mask air pressure is lower at other times during the therapy. Such is the case, for example, 30 when using auto-titrating or variable pressure systems or during ramp-up when using CPAP systems. Thus, the strap tension is higher than necessary during significant portions of the therapy duration. Further, since leaks are disruptive of both the

sleeping cycle and the prescribed therapy regimen, patients will often tighten the straps even more than is necessary to prevent leaks at the maximum encountered air pressure. In known masks, this higher than necessary strap pressure directly results in a higher than necessary force of the mask cushion on the patient's face, particularly as 5 the pressure goes below the maximum mask air pressure.

See Figure 1, which shows a force diagram for a known mask 110 having a cushion 130 attached to a rigid shell 120. The cushion 130 includes a face-contacting portion 134 attached to a cushion sidewall 173. The cushion sidewall 173 can be 10 relatively flexible, as in the ResMed Bubble Cushion® mask, or relatively rigid, as in the ResMed Mirage® mask. Although the mask 110 would be in contact with the face 42 of a patient 40 (shown in phantom) in use, for purposes of clarity in this diagram 15 (as well as the diagram of Figure 10), a flat foundation 43 is substituted for the patient's face 40. The total force of prior art masks on the user's face F_m has been found empirically to be given by the equation $F_m = F_c + F_{Ac}$, where F_c is the force of 20 the cushion on the patient's face and F_{Ac} is the force on the patient's face of the mask air pressure P inside of the perimeter of A_c , the area of contact of the cushion with the patient's face. The force F_{Ac} is given by the equation $F_{Ac} = PA_c$. Since the force F_c is distributed around A_c and is not merely located at two points on the cushion, as it 25 might seem due to the limitations of the two-dimensional representation of Figure 1, this force is shown in parentheses. Although A_c is shown inward of the sidewall 173 as would be the case if the mask 110 had just been brought into contact with the user's face with a minimal contacting force, in practice, the face-contacting portion 134 tends to roll under when sufficient force is applied to the mask 110 to seal the mask to the user's face such that A_c can expand outward, toward the sidewall 173.

The force (tension) in the headgear strap F_s for the prior art mask has been found empirically to be given by the equation $F_s = (F_c + F_{Ac})/(2\cos\theta)$, where θ is the angle of the head strap with respect to the mask 110. Thus, the force of the cushion on 30 the patient's face F_c is given by the equation $F_c = 2F_s\cos\theta - F_{Ac}$. The force of the mask cushion on the patient's face is difficult to distribute completely evenly around the cushion in known masks, especially at higher forces, and results in localized high

pressure spots around the mask cushion. This higher force on the face, and especially the localized high pressure spots, are uncomfortable to the patient and can disrupt the sleep cycle. See, for instance, Figure 2, which charts the force required to secure a mask on a face versus the air pressure in the mask (measured in centimeters H₂O). As 5 seen there, the force required to maintain a known mask sealed to the face throughout a mask air pressure range is most substantially affected by the maximum air pressure in the mask that will occur during therapy. That is, the force of the mask on the face remains at a fairly high level even when the pressure in the mask drops and this force of the mask on the face is directly related to the force necessary to seal the mask at the 10 maximum mask air pressure. Misalignment of the mask will move the curve upward as higher forces are required to seal the mask to the face in light of the misalignment.

This force on the face increases as the head straps of a known mask are tightened to increase the sealing force of the mask, and thereby compressing the 15 cushion and bringing the shell of the mask closer to the patient's face. When the straps are tightened, the shell of the mask moves a distance X between a position X_0 when a seal is first obtained to a position X_p when it reaches the point where the cushion is being compressed beyond its normal range. The mask shell may be able to move beyond X_p but the cushion tends to become rigid or nearly so at about X_p , thereby 20 limiting further travel. In a known mask, F_c generally increases at a first rate (i.e., the slope of the curve) as the mask moves toward the patient's face within a given range of X. This first rate occurs within the range of flexibility of the face-contacting portion 134. This first rate is also a function of the pressure in the mask acting on a back side 25 of the face-contacting portion 134 of the mask. Thus, as the pressure in the mask increases, the first rate also increases within the given range of X.

However, the known cushion becomes less flexible as it is further compressed beyond such range of X. In a mask having a more flexible sidewall, as discussed above, F_c will then increase at a faster rate as the mask moves toward the patient's 30 face due to a spring-force imparted by the sidewall until such point as the sidewall is nearly completely compressed and directly passing on the force from the rigid mask shell to the face. In a mask having a more rigid sidewall, as discussed above, F_c will

then increase at an even faster rate for a short distance as the mask moves toward the patient's face but will quickly reach a point where the rigid sidewall is directly passing on the force from the rigid mask shell to the face.

5 See Figure 3, which charts the force required to secure a mask on a face versus the movement of the mask frame (shell) from a relaxed positioned toward the face. The solid curve of Figure 3 shows the force on the face for a known mask, such as the ResMed Mirage® mask, at a mask air pressure of 10 cms H₂O. It can be seen from this curve that the force on the face increases in generally linear proportion to the
10 movement of the mask towards the face within the range of flexibility the cushion 130. However, at such point where the cushion is nearly completely compressed (at approximately 5-7 mm in Figure 3) so that the generally rigid sidewalls of the cushion 130 begin directly transferring the force from the rigid shell 120 to the face, the force on the face increases dramatically as the mask shell moves toward the face.

15 U.S. Patent Nos. 5,492,116 and 5,655,527 to Scarberry disclose a full-face respiratory mask. The mask includes a flexible seal member 18 directly attached to a mask shell 12 and is attached to the user's head by head gear 24. The flexible seal member 18 itself contacts the user's face with a broad area of contact and maintains a
20 seal with the user's face through pressure in the space 62 acting directly upon seal membrane inner surface 54.

25 Japanese Provisional unexamined patent application (Laid-open Kokai) published January 6, 1999 entitled NASAL MASK FOR RESPIRATION, Provisional Publication No. 11-397 discloses a bellows-formed elastic body between a mask shell and cushion. As seen in the figures of that publication, the bellows portion of the mask projects an area over the patient's face that is substantially the same as the contact area defined by the line of contact of the mask cushion with the patient's face. This publication teaches nothing about the relationship between the area of the
30 bellows and the force applied to the patient's face. Although the bellows provides limited mechanical flexibility, no significant pressure advantages or significant mechanical flexibility can be achieved. This mask does not overcome the sealing

problems incurred by movement of the mask with respect to the patient's face without utilizing an increased head strap pressure across the mask air pressure operating range.

SUMMARY OF THE INVENTION

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In one aspect, the invention provides a mask system including a shell which in use is positioned in a predetermined position relative to a patient's face, a face-contacting cushion which in use transfers a force to the patient's face, and a means for permitting relative movement between the cushion and the shell wherein said means 10 provides a predetermined force on the cushion. In one form, the predetermined force is a function of mask pressure. In another form, the predetermined force is a function of the displacement of the shell relative to the face. In another form, the predetermined force is a function of both mask pressure and displacement of the shell relative to the face. In another form, the predetermined force is independently controlled. In another 15 form, the means for permitting relative movement between the cushion and the shell is provided by a gusset section positioned in-between the shell and the cushion.

In one aspect, the invention provides a mask system including a face-contacting cushion having a first projected area on the face, a mask shell and a gusset 20 section therebetween, the gusset section having a second projected area on the face wherein the second projected area is greater than the first projected area by greater than approximately 30%.

In another aspect the invention provides a mask system for use at a mask 25 pressure including headgear coupled to a shell which exerts forces on the shell and a face-contacting cushion which transfers forces to the face, constructed and arranged so that the force transferred from the face-contacting cushion to the face is a strong function of mask pressure. The greater projected area of the gusset arrangement with respect to the face contacting area of the cushion uses the air pressure in the mask to 30 expand the gusset into contact with the patient's face, even when the mask shell changes alignment with the patient's face, to provide a more secure seal between the mask and the patient. The expansion, contraction and bending of the gusset allows for

enhanced mechanical flexibility over known mask arrangements that helps to maintain a seal even when the patient moves significantly during sleep and the position of the mask with respect to the patient's face changes. Thus, the force of the mask on the face is most significantly proportional to the mask air pressure and the cushion is

5 maintained in secure sealing contact with the patient's face by the mask air pressure over a broader range of positioning of the mask with respect to the patient. This allows for the tension in the straps of the headgear to be generally less than with a known mask to securely seal the mask to the patient's face, especially at mask air pressures below the maximum mask air pressure for the therapy, providing greater

10 patient comfort and compliance with the prescribed respiration therapy regime.

While some membrane-type cushion mask arrangements accommodate limited relative movement between the cushion and the wearer's face while maintaining a tolerable seal, the present invention dramatically increases the level of

15 accommodation without a corresponding increase in the head strap pressure used to secure the mask to the patient. The gusset section provides a flexible component between the mask shell and the cushion in contact with the user's face while reducing the tension required in the headgear to maintain the seal.

20 Other embodiments of the present invention provide new mask cushion configurations that assist in maintaining the seal between the mask cushion and the user's face.

Another embodiment of the present invention includes the use of a novel baffle element positioned within the interior space of the mask arrangement. The employment of a baffle member within the mask of the present invention minimizes short-circuiting of the intake gas directly to the exhaust vent with the resulting buildup of carbon dioxide. Thus, the baffle serves to reduce the functional dead space of the mask and reduce the level of carbon dioxide rebreathing by the patient.

30 With the foregoing in mind, other objects, features and advantages of the present invention will become more apparent upon consideration of the following

description and the appended claims with reference to the accompanying drawings, all of which form part of this specification, wherein like reference numerals designate corresponding parts in various figures.

5

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 shows a force diagram for a known mask;

10 Figure 2 charts the force required to secure both known and present invention masks on a patient's face versus the air pressure in the mask;

Figure 3 charts the force required to secure both known and present invention masks on a patient's face versus the movement of the mask shell from a relaxed positioned toward the patient's face;

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Figure 4 shows a side elevational view of a mask of the present invention;

Figure 5 shows a perspective view of the mask of Figure 4;

20 Figures 6-7 are partial sectional views of the gusset portion of the mask of Figure 4 before and after inflation;

Figure 8 is an end elevational view of a mask shell side of the gusset portion of the mask of Figure 4;

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Figure 9 is a partial sectional view of the cushion of the mask of Figure 4;

Figure 10 shows a force diagram of the mask of Figure 4;

30 Figure 11 is a perspective view of a mask of the present invention attached to a patient using strap-based headgear;

Figure 12 is a partial sectional view of an alternative embodiment of the gusset portion of the present invention;

5 Figure 13 is a partial side elevational view of an alternative embodiment of the gusset portion of the present invention;

Figure 14 is a partial sectional view of an alternative embodiment of the gusset portion of the present invention;

10 Figures 15-18 show sectional views of alternative embodiments of the mask of the present invention in contact with a patient's face;

15 Figure 19 diagrams the key characteristics, principal advantages and patient benefits deriving from the present invention and leading to increased therapy compliance by the patient;

Figure 20 shows an elevational view of the interior of the mask shell of one embodiment of the present invention;

20 Figure 21 shows a diagrammatic view of an alternative embodiment of the present invention;

Figure 22 shows a diagrammatic view of an alternative of the embodiment shown in Figure 21;

25 Figure 23 shows a partial sectional view of one alternative of the embodiment of Figure 21;

Figure 24 shows a partial sectional view of another alternative of the 30 embodiment of Figure 21; and

Figures 25-30 show partial sectional views of alternative embodiments of a mask cushion of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

5

A first embodiment of the respiratory mask 10 of the present invention is shown in Figures 4-9. The mask 10 includes a generally rigid shell 20 having an air tube 22 for connecting to a pressurized air supply 23. A gusset portion 32 is attached to the shell 20 in a known manner such as gluing or mechanical fastening. The gusset portion 32 acts as a suspension mechanism for a cushion 30 and includes a flexible gusset sidewall 33. A partial sectional view of the gusset portion 32 is shown in Figure 6. In this embodiment, the gusset sidewall 33 has a generally uniform thickness and the gusset portion 32 has a generally triangular cross-section when not exposed to mask pressure. However, in this embodiment, the flexible sidewall 33 will balloon out 10 when the mask 10 is pressurized to take on the more rounded cross-section shown in Figure 7. The Figure 8 end view of the gusset portion 32 shows that the gusset has a generally triangular outline to conform with the shape of the cushion 30 and shell 20. 15

Cushion 30 includes a face-contacting portion 34 that is adapted to engage the 20 face 42 of a patient (user) 40 as shown in Figure 10. The face-contacting portion 34 of the cushion 30 can be in the form of a standard cushion, such as the ResMed Standard Cushion, or can be in the form of the prior ResMed Bubble Cushion® and Mirage® cushions discussed above or in another form as the circumstances warrant. In the preferred embodiment, shown in a partial sectional view in Figure 9, the cushion 30 of 25 the present invention incorporates an outer membrane 70 that acts as the face contacting portion 34 and an inner rim 72 that provides a backing element for the membrane 70, as does the ResMed Mirage® mask. Both the outer membrane 70 and the inner rim 72 are connected to a relatively rigid sidewall 73 that connects with the flexible gusset portion 32. In a worn position, the mask encompasses the nares of the 30 patient and provides a seal around the nose 44. In alternative embodiments, the mask can also enclose both the nose 44 and the mouth of the patient, just the mouth of the patient or the entire face. A headgear 50 (see Figure 11) having adjustable tensioning

straps 52 engages the shell 20 and is used to secure the mask 10 to the patient 40. In the preferred embodiment of the present invention, the headgear and tensioning straps are adjustable as to size but relatively inextensible once adjusted. Mask shell 20 includes an exhaust vent 21 for exhausting gases from the mask and a baffle 23 which

5 will be discussed in further detail below.

The gusset portion 32 includes two key characteristics that provide the benefits of one embodiment of the present invention. The first key characteristic of the gusset portion 32 is that it utilizes the pressure in the mask acting on its increased surface area to provide the primary force for maintaining the face-contacting portion of the cushion in sealing contact with the user's face. The second key characteristic of the gusset portion is that it provides a decoupling joint between the face-contacting portion 34 of the cushion 30 and the mask shell 20, thus allowing some relative movement between the mask and the user's face. This arrangement substantially

10 protects the seal from undue disturbance in the following scenarios: 1) displacement or tilting of mask shell or harness; 2) relaxation of the facial muscles; 3) movement of the patient; and/or 4) movement of the tube. Figure 11 shows one embodiment of the mask of the present invention attached to a patient.

15

20 Figure 10 shows a force diagram representative of the mask embodiment shown in Figures 4-9 (as well as various alternative embodiments of the present invention discussed below). Figure 10 shows A_c , the area of contact of the cushion with the patient's face and A_g , the area defined by the gusset portion 32, for the present invention mask.

25 The area A_g is a projected area on the user's face (i.e., projected on a plane normal to an axis of the mask) of an interior of the gusset portion 32 exposed to the mask air pressure. In the embodiment shown in Figures 4-10, A_g extends to the outermost interior surface of the sidewall 33 of the gusset portion 32 and includes A_c .

30 As can be seen, the addition of the gusset portion 32 to the mask 10 results in an area A_g being significantly greater with respect to the area A_c than is found in either the

prior ResMed® masks (see Figure 1) or the mask disclosed in Japanese Provisional Publication No. 11-397, discussed above.

The significance of this can be seen from the following. In one form of the 5 invention, the total force of the mask on the face F_m is given by the empirical equation $F_m = F_c + F_{Ac} = P(A_g - kX) = 2F_s \cos\theta$. The force of the cushion on the patient's face F_c is given by the empirical equation $F_c = P(A_g - A_c - kX)$. The force (tension) in the headgear strap F_s is given by the empirical equation $F_s = P(A_g - kX)/(2\cos\theta)$, where k is the spring constant for the elasticity of the gusset portion and X is the amount of 10 travel of the mask shell toward the face. Figure 10 also shows X_p , the working travel range of the gusset portion 32, although in practice, if the pressure in the mask pushes the face-contacting portion 34 away from the shell 20, X_p can be longer than is shown when the gusset is at rest.

15 Although k is usually not affected by pressure with respect to a purely mechanical spring, it has been found that within the pressure ranges occurring in the mask of the present invention, that k is proportional to both pressure and distance traveled. Thus, while in the present invention, the maximum force on the face F_m that could be expected to be exerted within X_p would be PA_g , testing has shown that this is 20 reduced by the k factor which is both proportional to pressure in the mask and distance travelled.

For a prior art mask configuration, it is seen from Figure 1 that the force in the headgear strap $F_s = (F_c + PA_c)/(2\cos\theta)$. For the present invention mask, it is seen from 25 Figure 10 that the force in the headgear strap $F_s = P(A_g - kX)/(2\cos\theta)$. The area defined by the gusset A_g is substantively larger than the area in contact with the face A_c . Therefore, at the point at which the cushion touches the face (the theoretical initial seal point when both $F_c = 0$ and $X = 0$), the force in the straps for the known mask will be $PA_g/(2\cos\theta)$ as opposed to $PA_g/(2\cos\theta)$ for the present invention mask. However, 30 in reality, a contact force F_c greater than zero is required to: 1) maintain the seal between the face and the cushion because the profiles of the face and cushion are not perfectly matched, and 2) maintain this seal during movement of the face relative to

the shell. This force is balanced by the tension in the headgear straps in the known mask system and balanced by the pressure acting upon the gusset area alone, $A_g - A_c$, in the present invention mask system. Thus, within the normal operating mask air pressure range, and especially at lower operating mask air pressures, it has been found 5 that the headgear tension F_s is lower in the present invention mask system.

From Figure 10, it can also be seen that for the present invention mask, the contact force between the cushion and the face is proportional to the mask pressure, $F_c = P(A_g - A_c - kX)$. This has significant implications in therapies where the mask air 10 pressure varies during either the course of a breath or breath-to-breath or to meet other therapeutic needs. With known mask configurations, where the force of the cushion on the face varies little, if at all, with respect to the pressure in the mask, the tension in the straps must be set sufficiently high at low pressures such that the contact force of the cushion on the face is sufficient to maintain the seal with the face when higher 15 pressures are reached.

For the present invention configuration, both the cushion contact force and the strap tension are significantly affected by the pressure in the mask due to the significantly increased area of the gusset. Therefore, as they both are most 20 proportional to the pressure in the mask, they both will be significantly lower at low pressures and increase as the pressure reaches higher pressures.

In fact, in practice, it has been found that this holds true even at maximum mask air pressures. As an example, assume that A_c is the same in both a known mask 25 (as, for instance, the ResMed Mirage® mask) and the inventive mask (both using, say, the same configuration in the face-contacting portion of the cushion). F_{Ac} would be the same in both cases. Then you might expect that given proper alignment of both masks, the minimum necessary F_c for sealing the masks at a given pressure would be the same in both the known and inventive masks and thus, the required F_m to seal at a 30 given pressure to be the same in both cases. However, testing has shown that the present invention mask will seal at a lower force on the cushion, a lower force on the face, and a lower tension in the straps, even at the maximum mask air pressure, than

the known mask. It is believed that the test results reflect the real world situation. That is, no face is identical and exactly conforms to the cushion and further, that it is extremely difficult to maintain exact alignment of the mask with the face. This is even more the case with older and/or overweight patient that have loose skin, wrinkles and/or skin folds that hamper the sealing of the mask to the face. Testing has shown that the present invention mask is better able to accommodate these inconsistencies from user to user and provide better sealing performance at lower forces on the face (even at the maximum mask air pressure) than the known mask.

10 See also the chart in Figure 3 that shows a comparison of the present invention mask and known masks with respect to the force on the face as the mask shell moves toward the face. As long as the present invention is within the range X_p of the gusset, there is no sharp increase in the force on the face as with the known masks as the mask shell approaches the face. Beyond X_p , the force on the face will increase more dramatically, as happens with the known mask, so it is desirable when adjusting the headgear to bring the face contacting portion of the cushion only near or in very light contact with the face. In this way, the gusset is not compressed substantially so that in use the mask is still within the X_p range. This is possible because the seal is maintained by the pressure in the mask and not by compression of the cushion by the headgear. Adjustment of the headgear and mask is thus much simpler than in the known masks. While the range of X_p can be varied for different patients and therapies by varying the size and shape of the gusset section, it has been found that an X_p of between 10-30 mm has been effective. It is noted that the curves shown in Figure 3 are for a mask air pressure of 10 gf/cm² (grams force/centimeter²) These curves can be expected to rise and lower as the mask air pressure is increased and decreased, respectively, but will generally maintain the same shape within the operating pressure range of the mask.

30 In one embodiment of the present invention shown in Figures 4-9, the gusset and cushion are integrally molded of Silastic® 94-595 HC Liquid Silicone Rubber from Dow Corning®, the gusset sidewall 33 has a uniform thickness of 0.5 mm, the gusset has a long length (of the generally triangular A_g) of approximately 105 mm and

the long length of the generally triangular A_c is approximately 71 mm. The X_p is approximately 25 mm. Thus, the gusset (A_g) extends generally beyond the face-contacting portion of the cushion (A_c) by approximately 17 mm on each side. This provides for approximate figures for the A_c of 31.5 cm^2 , the A_g of 75 cm^2 , a gusset only area ($A_g - A_c$) of 43.5 cm^2 and an A_g/A_c of approximately 2.4 (or 240%). These dimensions can be altered for different force relationships as desired, but in the preferred embodiments, A_g/A_c will be in the range of about 1.30-5.00 and desirably in the progressively narrowing ranges of 1.50-5.00, 2.00-4.00, and 2.25-3.50, but can be adjusted to fall within any range within the overall range of 1.30-5.00 or even within a range extending beyond that range if circumstances warrant. This compares with an estimated A_g/A_c for the mask example disclosed in Japanese Provisional Publication No. 11-397 discussed above of approximately 1.08.

In the preferred embodiment of the mask, the total force applied to the face F_m is approximately constant at between 35 to 108 grams per gf/cm^2 mask air pressure, preferably between about 40 to 88 grams per gf/cm^2 mask air pressure and most preferably between about 50 to 88 grams per gf/cm^2 mask air pressure. The force applied by the surface area in contact with the face F_c is maintained at an approximately constant proportion to the mask air pressure being delivered to the user and is maintained between about 8 to 61 grams per gf/cm^2 mask air pressure, preferably between about 27 to 61 gms per gf/cm^2 mask air pressure and most preferably between about 40 to 61 grams per gf/cm^2 mask air pressure over a mask air pressure range of 4 to 25 gf/cm^2 . The force F_c is also maintained within a range of about 0.3 – 4 grams per gf/cm^2 pressure of the supply of pressurized breathable gas per linear centimeter around a circumference of the cushion in contact with the user's face, preferably within a range of about 0.5 – 4 grams per gf/cm^2 pressure of the supply of pressurized breathable gas per linear centimeter around a circumference of the cushion in contact with the user's face, more preferably in a range of about 1 – 3 grams per gf/cm^2 pressure of the supply of pressurized breathable gas per linear centimeter around a circumference of the cushion in contact with the user's face, and most preferably in a range of about 1.5 – 3 grams per gf/cm^2 pressure of the supply of pressurized breathable gas per linear centimeter around a circumference of the cushion

in contact with the user's face over a mask air pressure range of 4 to 25 gf/cm². Although the preferred force ranges for the various forces are set forth in this paragraph, it should be recognized that the force ranges can be set between any two points within the respective overall force ranges given. It is noted that in the industry 5 of the present invention, most pressure measurements are given in centimeters water and that 1 centimeter water = 1 gf/cm² = 98.07 Pascals.

The gusset portion also allows the mask to maintain a seal with the patient's face over a range of about plus or minus 8° out of alignment with the patient's face.

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It has also been found that the shape of the curve for the inventive mask shown in Figure 3 can be varied by altering the cross-section of the gusset or by providing a backstop for the gusset. Where the gusset has a very uniform thickness and curve, as shown in Figures 6 and 7, the curve for total force on the face versus movement of the 15 mask toward the face will be generally linear within X_p. It has generally been found desirable in testing to apply a higher sealing force earlier as the mask shell travels toward X_p. That is, it is advantageous to move from C, the minimum force to seal at the given pressure, toward D, the minimum force for the inflated gusset, earlier in the travel of the mask shell toward X_p. This provides a greater remaining amount of X_p, 20 within which the mask will operate and a more gradual increase of the force of the mask on the face as the mask shell moves toward X_p within the remaining amount. The embodiments shown in Figures 12-14 help accomplish this goal.

In the first example, shown in Figure 12, the bases of the gusset sidewall are 25 thickened in an abrupt manner to stiffen the sidewall. In this embodiment, the force-displacement curve for the mask generally follows the curve for the cushion (i.e., the curve for the known mask shown in Figure 3) as it moves from C toward D and then a lower, generally linear slope until reaching X_p. See the long-dashed curve in Figure 3. However, changing the value for D can alter this curve. The value for D is calculated 30 by multiplying the area for the stiffened portion of the gusset sidewall by the pressure in the mask. The stiffened portion of the gusset sidewall is shown as A_s in Figure 10. If however, the value of A_s is increased by stiffening a greater portion of the gusset

sidewall, the value of D will increase. See the value for D' shown in Figure 3 and the short-dashed curve that corresponds to a mask embodiment where a greater portion of the gusset sidewall has been thickened (stiffened) to increase A_s . Thus, the long-dashed curve represents a gusset embodiment as shown in Figure 12 having an A_{s1} and the short-dashed curve represents a gusset embodiment as shown in Figure 12 having an A_{s2} greater than A_{s1} . It can be seen from Figure 3 that the gusset embodiment having the A_{s2} has reached the value D' much sooner as the mask shell moves toward X_p than the gusset embodiment having the A_{s1} , thereby leaving a greater remaining amount of the range X_p within which the mask shell can move in use.

A similar effect can be obtained by adding rigid backstops to the embodiment of Figures 6 and 7. See Figure 13, which shows an embodiment where rigid backstops 35 are attached to one or both of the gusset portion 32 and the shell 20. The rigid backstops contact the sidewalls of the gusset in the inflated mode and act as stiffeners to the portions of the sidewall that are contacted. Thus, the rigid backstops can provide the same effect as the embodiment of Figure 12. The backstops 35 can be placed on one or both sides of the gusset portion and can extend around either a portion, or all, of the perimeter of the gusset portion, as is necessary to provide the desired curve. The backstops can be made of the same material as the mask shell 20 and in one embodiment, one or both backstops 35 can be molded integrally with the shell 20. In alternative embodiments, the configurations shown in Figures 6, 7, 12, 14 and 16 can be used in combination with one another, i.e., one configuration on one side of the gusset and another configuration on the other side of the gusset, to specifically tailor the force/travel curve as desired. The thicknesses and dimensions of the various embodiments can also be altered to specifically tailor the force/travel curve. This ability to readily and specifically tailor the force/travel curve of the mask by altering gusset configurations and dimensions is another unique and advantageous aspect of the present invention.

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Where the gusset has sidewalls having a tapered thickness, as shown in Figure 14, the resulting force-displacement curve will lie between the curve for the

embodiment of Figure 6 and the curve for the embodiment of Figure 12 (assuming comparable gusset base and intermediate thicknesses for the two embodiments).

The gusset portion need not be in the single gusset form discussed above, but 5 can have alternative configurations, examples of which are shown in Figures 15-18, along with the A_c and A_g for each example.

Figure 15 shows an alternative embodiment of the mask 10 where the gusset portion 32 is in the form of a double gusset providing the decoupling joint between the 10 face-contacting portion 34 of the cushion 30 and the mask shell 20. Of course, three or more gussets can be used in alternative embodiments of the gusset portion 32. Figure 16 shows an alternative embodiment of the mask 10 where the gusset portion 32 is in stepped form to provide the decoupling joint between the face-contacting portion 34 of the cushion 30 and the mask shell 20. While three steps are shown in Figure 16, one 15 or more steps can be used in alternative embodiments. One advantage of this embodiment of gusset is the ease in molding the gusset portion 32 and cushion 30 together, since the shell side of the gusset portion 32 is completely open, i.e., there are no hidden surfaces. Figure 17 shows an alternative embodiment of the mask 10 where the gusset portion 32 is in the form of a piston 54 at the base of the cushion 30 axially 20 slideably engaged with a cylinder portion 56 of the shell 20. The piston 54 can thus move the cushion 30 in and out of the shell 20 to provide a decoupling joint between the face-contacting portion 34 of the cushion 30 and the mask shell 20. A stop 58 can be provided on the shell 20 to prevent the piston and cushion from completely 25 disengaging with the shell 20 under pressure. A spring 60 can optionally be provided to push the piston 54 back into the shell 20 when the air pressure in the mask is decreased. The existence of the spring also simulates the elastic resistance of the gusset portions discussed above and adding a kX factor to the F_m equation. Without the spring, k would equal 0 within the range of movement of the piston.

30 Yet another alternative mask configuration is shown in Figure 18 which includes a gusset portion 32 having a larger upper barrel shaped gusset 78 and a lower smaller barrel shaped gusset 80. Alternatively, the larger and smaller gussets can be

reversed, made the same size or even given different configurations to custom tailor the force characteristics.

Figure 21 shows an alternative embodiment of the mask of the present invention wherein the gusset portion 32 has a flexible sidewall 33 having a generally circular or round cross-section enclosing a gusset chamber 190 having an interior volume separated from an interior 192 of the mask shell 20. In one version of this embodiment the gusset chamber 190 can be connected to the mask shell interior 192 through at least one port 193 in the sidewall 33. See Figure 23. In such a case, a pressure P_2 in the gusset chamber will be the same as a pressure P_1 in the interior of the mask shell, the effective area of the gusset portion 32 A_g will extend to the outermost interior surface of the gusset sidewall 33, and the gusset portion will operate similarly to the embodiment shown in Figure 10. However, in a preferred version of this embodiment, the interior of the gusset chamber 190 is connected through a port in the sidewall 33 to a separate pressurized supply of gas than is connected to the mask shell interior so that the pressure P_2 in the gusset chamber 190 can be controlled to be at a different pressure than the pressure P_1 in the mask shell interior 192. Thus, the force imparted by the gusset portion will be a product of the pressure P_2 and the area of the gusset portion. Further, in this embodiment, the area of the gusset portion is no longer determined by the outermost interior surface of the gusset sidewall as in the previous embodiments, but will be the projected area of the entire gusset chamber 190, including the area of the gusset chamber radially inward from the cushion sidewall. This area of the gusset chamber A_{gc} is shown in parentheses in Figure 21. This provides a high degree of flexibility in controlling the gusset portion and the mask.

First, if additional sealing force is needed from the gusset portion, the pressure P_2 can merely be increased, or vice-versa if less sealing force is needed. Second, since the force imparted on the cushion by the gusset portion is a product of the pressure P_2 and the area of the gusset portion A_{gc} , the area A_{gc} is less critical than in the previous embodiments because it can be offset by changes in the pressure P_2 . For instance, the outer periphery of the gusset portion can be made smaller in this embodiment than in

the previous embodiments because an interior portion of the gusset portion is now also adding to the pressurized area of the gusset portion. Further, the area A_{gc} of the gusset chamber can be varied as desired, and especially made smaller, by varying the pressure P_2 . This allows the mask to be made smaller, as compared to the other masks discussed above, to be less intrusive and more comfortable to the patient.

5. The pressure P_2 can be controlled to be in relatively constant proportion to P_1 or can be controlled to be in varying proportion to P_1 as the circumstances warrant. While it is currently believed that in most therapies, P_2 will be greater than P_1 for 10 most, if not all, of the therapy, it is contemplated that in certain situations, controlling P_2 to be less than P_1 can be desirable. In some instances, it is contemplated that P_2 be held constant. The gusset chamber in this embodiment is intended to be connected only to the second pressurized gas supply and otherwise be closed, especially to the atmosphere. Thus, there should be minimal leakage from the gusset chamber and the 15 second pressurized gas supply need only supply a small volume of gas, significantly less than the volume of gas that must be supplied for breathing purposes by the first pressurized gas supply. Further, the two separate pressurized gas supply sources for P_1 and P_2 can be provided by the same single gas pump and controlled by known control devices to be at the different desired pressures, or alternatively, two separate gas 20 pumps can be used for the gas supplies to the mask interior 192 and the gusset chamber 190, respectively, to separately control each of P_1 and P_2 .

The gusset chamber 190 can be connected to the second gas supply through a 25 port 194 in the gusset sidewall 33 connecting with a port 195 integrally molded with the mask shell 20 or can bypass the mask shell 20 and connect to the second gas supply through a port 196 in the gusset sidewall 33. See Figure 24, which shows both alternatives.

The embodiment of Figure 21 can have portions of the gusset sidewall 32 30 thickened/stiffened as discussed above with respect to Figures 12-14. However, the increased flexibility offered by controlling P_2 differently from P_1 means that the gusset sidewall can also be made generally uniform in thickness and a similar effect provided

by the stiffening in the previously described embodiments can be provided in this embodiment merely by altering the pressure P_2 as desired.

In an alternative embodiment of the mask shown in Figure 21, the gusset 5 portion 32 can have a generally diamond-shaped cross-section when the mask 10 is not in use or not pressurized, as shown in Figure 22, which cross-section can balloon to a generally circular cross-section when the gusset chamber is pressurized. Alternative shapes for the gusset portion 32 can also be used, including a piston/cylinder arrangement corresponding to Figure 17 discussed above.

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The cushion can also have alternative configurations. See Figures 25-30, which show partial sectional views of the cushion 30. In each of these embodiments, the cushion 30 is provided with a flexible membrane 170 that acts as a face-contacting portion 134. The flexible membrane 170 is attached to the more rigid supporting 15 sidewall 173 of the cushion 30. These embodiments do not use an inner rim as does the embodiment shown in Figure 9. In each embodiment, the face-contacting portion 134 extends beyond an axially outer end 174 of the sidewall 173 when the cushion is at rest. The face-contacting portion 134 can move axially with respect to the sidewall 173 to alter an axial distance between the face-contacting portion 134 and the axially 20 outer end 174. That is, when a force is applied to the cushion toward the users' face, the face-contacting portion 134 will retract, axially moving toward the axially outer end 174 of the sidewall 173. The axially outer end 174 of the sidewall 173 will provide a generally positive end limit to this retraction when it contacts the user's face.

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In the embodiments shown in Figures 25 and 26, the flexible membrane 170 is attached to the sidewall 173 at a position 175 axially inward from the axially outer edge 174, with a portion of the flexible membrane 170 extending axially outwardly alongside the sidewall 173 between the position 175 and the axially outer edge 174. In 30 these embodiments, axial movement of the face-contacting portion 134 is substantially provided by the flexibility of the flexible membrane 170. If a less rigid sidewall 173 is desired, for instance, to be more comfortable to the user when the axially outer edge

174 contacts the user's face, the sidewall 173 can have a hollow portion 176, especially between the position 175 and the axially outer edge 174. See Figure 26.

In the embodiments shown in Figures 27-30, the flexible membrane 170 is

5 connected to the sidewall 173 by a flexible connecting member 177 that provides for axial movement between the flexible member 170 and the sidewall 173. The flexible connecting member 177 can have a generally straight cross-section, as seen in Figure 27, a convoluted cross-section, as seen in Figure 28, or another cross-section. The flexible connecting member 177 can be attached to the sidewall 173 near the axially outer end 174, as shown in Figures 27-29, or can be attached to the sidewall 173 at an axially inward position 175, as shown in Figure 30. As with the embodiment of Figure 10 26, the sidewall can be at least partially hollow to make the sidewall less rigid. See Figure 29. In the preferred embodiment, the flexible membrane 170, the flexible connecting member 177 and the sidewall 173 are integrally molded together.

15 Although the flexible membrane is shown as being attached to a cushion sidewall, it is contemplated that in alternative embodiments, the flexible membrane can be attached directly to the mask shell, with a portion of the mask shell acting as the axially outer edge 174.

20 The embodiments of Figure 25-30 can be used in conjunction with the gusset feature described above or can be used with known mask cushions. These embodiments provide good sealing characteristics with the face in a cushion that is easier and less expensive to manufacture than the known mask cushions. It is also to be understood that in the embodiments of Figures 27-30, the flexible connecting member 177 can act similarly to the gusset feature described above when the mask is pressurized. That is, the pressure in the mask will act on the flexible connecting member 177 to impart an additional force on the face-contacting portion 134 of the flexible membrane 170 and that additional force will have the same characteristics as described above with respect to the above-described embodiments. In the 25 30 embodiments of Figures 27-30, the area A_c would be measured the same as in the embodiments above and the area A_g would be measured to the interior surface of the sidewall 173 where the flexible connecting member 177 attaches to the sidewall 173.

Other alternative embodiments can use various combinations of any of the embodiments disclosed herein.

5 It should be recognized that the gusset portion of the present invention can be manufactured as a component separate from the cushion and mask shell but is attachable therebetween to provide the benefits described herein.

10 The reduced contact force, total force on the face and headgear tension across the mask air pressure range and especially at mask air pressures below the maximum mask air pressure improves patient comfort, in particular for auto-titrating devices which start therapy at low pressures at the beginning of the night when the patient is trying to get to sleep. The improved seal (which can be obtained with a lower contact force) reduces sleep disturbance to patients and partners by substantially reducing the 15 risk of leaks. The improved seal also increases the confidence of the patient in the seal, resulting in more comfortable therapy for the patient. See Figure 19, which diagrams how the key characteristics of the gusset portion of the present invention mask provide principal advantages leading to patient benefits and improved compliance with a prescribed therapy.

20 Another aspect of the present invention is the inclusion of the baffle 23 in the mask shell 20. The employment of the baffle in the mask shell 20 improves the movement of air within the mask. In the embodiment shown in Figures 4, 5 and 20, the baffle 23 is in the form of a flat plate disposed between the mask intake 22 and the 25 mask exhaust vent 21. The baffle 23 can extend into the mask generally horizontally or can tilt upward or downward. The baffle need not be in the form of a flat plate but can be V-shaped, curved, wavy or have some other configuration best designed to deflect air from the intake from directly flowing to the exhaust vent. The baffle 23 can be integrally molded with the mask shell or attached to the shell by other known 30 methods, including adhesive or ultrasonic bonding. It should be understood that the mask shell incorporating the baffle can be used in combination with the gusset

portion, but that either of these aspects can be used alone in a mask of the present invention.

While the invention has been described in accordance with what is presently 5 believed to be the most practical and preferred embodiments, it is to be understood that the invention is not to be limited to the disclosed embodiments but on the contrary, is intended to cover various modifications and equivalent arrangements included within the spirit and the scope of the appended claims, which claims are to be interpreted in the broadest manner so as to encompass all such equivalent structures.

CLAIMS:

1. A breathable gas mask arrangement, comprising:
 - a mask shell having a portion adapted to receive a supply of pressurized
 - 5 breathable gas and a user side;
 - a gusset portion having a first side attached to the user side of the shell and having a second side;
 - a cushion having a first portion constructed and arranged to attach to the second side of the gusset portion and a second portion constructed and arranged to
 - 10 contact a user's face in use and provide a seal between the mask arrangement and the user's face; and
 - a headgear constructed and arranged to attach the mask shell to the user;
 - wherein, the gusset portion is constructed and arranged such that it can expand and contract to alter a distance between the mask shell and the cushion, an interior of
 - 15 the gusset portion being exposed to the supply of pressurized breathable gas and having a projected area on the user's face A_g which is greater than an area A_c of contact of the cushion with the user's face such that the supply of pressurized breathable gas acting on the area A_g provides a component of a contact force F_c of the cushion on the user's face, and a ratio of A_g/A_c is at least 1.30.
- 20 2. A breathable gas mask arrangement as in claim 1, wherein the ratio of A_g/A_c is in a range of 1.50 to 5.00.
3. A breathable gas mask arrangement as in claim 2, wherein the ratio of A_g/A_c is
- 25 in a range of 2.00 to 4.00.
4. A breathable gas mask arrangement as in claim 3, wherein the ratio of A_g/A_c is in a range of 2.25 to 3.50.
- 30 5. A breathable gas mask arrangement as in claim 1, wherein the gusset portion can expand and contract to alter the distance between the mask shell and the cushion by at least 15 mm.

6. A breathable gas mask arrangement as in claim 5, wherein the gusset portion can expand and contract to alter the distance between the mask shell and the cushion by at least 20 mm.

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7. A breathable gas mask arrangement as in claim 1, wherein the gusset portion includes a single gusset having a flexible sidewall with a generally triangular cross-section when not exposed to the supply of pressurized breathable gas that balloons to a generally rounded cross-section when exposed to the supply of pressurized breathable gas.

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8. A breathable gas mask arrangement as in claim 7, wherein the gusset portion includes a plurality of interconnected gussets having flexible sidewalls with generally triangular cross-sections when not exposed to the supply of pressurized breathable gas that balloon to generally rounded cross-sections when exposed to the supply of pressurized breathable gas.

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9. A breathable gas mask arrangement as in claim 1, wherein the gusset portion includes a plurality of sequentially interconnected steps moving from larger to smaller in area between the first and second sides of the gusset portion, respectively.

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10. A breathable gas mask arrangement as in claim 1, wherein the mask shell includes an axially extending cylinder portion and the gusset portion is in the form of a piston axially slideably engaged with the cylinder portion of the mask shell.

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11. A breathable gas mask arrangement as in claim 10, and further including a spring engaged between the mask shell and the piston to apply a retracting force between the mask shell and the piston.

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12. A breathable gas mask arrangement as in claim 11, wherein the mask shell includes a stop portion for engaging the piston to limit axial movement of the piston.

13. A breathable gas mask arrangement as in claim 1, wherein the gusset portion includes a plurality of interconnected gussets, at least two of the gussets having differently sized areas exposed to the supply of pressurized breathable gas.
- 5 14. A breathable gas mask arrangement as in claim 1, wherein the gusset portion includes a sidewall having a thickened cross-section at a base of the sidewall.
15. A breathable gas mask arrangement as in claim 14, wherein the thickened portion has a generally uniform thickness.
- 10 16. A breathable gas mask arrangement as in claim 14, wherein the gusset portion includes a sidewall having a cross-sectional thickness tapering from a thickened base portion to a thinner portion.
- 15 17. A breathable gas mask arrangement as in claim 1, and further including a generally rigid backstop attached to the mask shell for contacting a first sidewall portion of the gusset portion to limit movement of the first sidewall portion.
18. A breathable gas mask arrangement as in claim 17, wherein the generally rigid backstop extends around substantially an entire periphery of the gusset portion.
- 20 19. A breathable gas mask arrangement as in claim 18, and further including a generally rigid second backstop attached to the mask shell for contacting a second sidewall portion of the gusset portion to limit movement of the second sidewall portion.
- 25 20. A breathable gas mask arrangement as in claim 1, wherein the mask shell further includes a baffle disposed in an interior of the mask shell between a mask gas intake and a mask exhaust vent to deflect gas from the intake from directly flowing to the exhaust vent.
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21. A breathable gas mask arrangement as in claim 20, wherein the baffle is in the form of a flat plate tilted away from a horizontal axis of the mask.
22. A breathable gas mask arrangement as in claim 1, wherein the gusset portion 5 has a flexible sidewall with a generally circular cross-section enclosing an interior volume and at least one port connecting the interior volume of the gusset portion to the supply of pressurized breathable gas.
23. A mask for delivering breathable gas to a patient, comprising:
 - 10 a mask shell having a portion adapted to receive a supply of pressurized breathable gas and a user side;
 - 15 a gusset portion having a first side attached to the user side of the shell and having a second side;
 - 20 a cushion having a first portion constructed and arranged to attach to the second side of the gusset portion and a second portion constructed and arranged to contact a user's face in use and provide a seal between the mask and the user's face; and
 - 25 a headgear constructed and arranged to attach the mask shell to the user; wherein, the gusset portion is constructed and arranged such that it can expand and contract within a range of displacement to alter a distance between the mask shell and the cushion, the gusset portion defining a gusset area exposed to the supply of pressurized breathable gas in use such that the supply of pressurized breathable gas acting on the gusset area provides a component of a contact force F_c of the cushion on the user's face, the force F_c being maintained in approximately constant proportion to the supply of pressurized breathable gas and a total force of the mask on the face F_m being maintained within a range of about 35 - 108 grams per gf/cm^2 pressure of the supply of pressurized breathable gas over an operating pressure range of the mask.
24. A mask for delivering breathable gas to a patient as in claim 23, wherein the 30 force F_m is maintained within a range of about 40 - 88 grams per gf/cm^2 pressure of the supply of pressurized breathable gas.

25. A mask for delivering breathable gas to a patient as in claim 24, wherein the force F_m is maintained within a range of about 50 – 88 grams per gf/cm^2 pressure of the supply of pressurized breathable gas.

5 26. A mask for delivering breathable gas to a patient as in claim 25, wherein the operating pressure range is about $4-25\text{ gf/cm}^2$.

27. A mask for delivering breathable gas to a patient as in claim 26, wherein the expansion and contraction of the gusset portion permits a seal to be maintained
10 between the cushion and the user's face within a range of about plus and minus 8 degrees angular displacement of the mask shell with respect to the user's face.

15 28. A breathable gas mask arrangement as in claim 23, wherein the gusset portion includes a single gusset having a flexible sidewall with a generally triangular cross-section when not exposed to the supply of pressurized breathable gas that balloons to a generally rounded cross-section when exposed to the supply of pressurized breathable gas.

20 29. A breathable gas mask arrangement as in claim 23, wherein the gusset portion includes a sidewall having a thickened cross-section at a base of the sidewall.

30. A breathable gas mask arrangement as in claim 29, wherein the thickened portion has a generally uniform thickness.

25 31. A breathable gas mask arrangement as in claim 29, wherein the gusset portion includes a sidewall having a cross-sectional thickness tapering from a thickened base portion to a thinner portion.

30 32. A breathable gas mask arrangement as in claim 23, and further including a generally rigid backstop attached to the mask shell for contacting a first sidewall portion of the gusset portion to limit movement of the first sidewall portion.

33. A breathable gas mask arrangement as in claim 32, wherein the generally rigid backstop extends around substantially an entire periphery of the gusset portion.

34. A mask for delivering breathable gas to a patient, comprising:

5 a mask shell having a portion adapted to receive a supply of pressurized breathable gas and a user side;

a gusset portion having a first side attached to the user side of the shell and having a second side;

10 a cushion having a first portion constructed and arranged to attach to the second side of the gusset portion and a second portion constructed and arranged to contact a user's face in use and provide a seal between the mask and the user's face; and

a headgear constructed and arranged to attach the mask shell to the user;

15 wherein, the gusset portion is constructed and arranged such that it can expand and contract within a range of displacement to alter a distance between the mask shell and the cushion, the gusset portion defining a gusset area exposed to the supply of pressurized breathable gas in use such that the supply of pressurized breathable gas acting on the gusset area provides a component of a contact force F_c of the cushion on the user's face, the force F_c being maintained within a range of about 8 – 61 grams per 20 gf/cm^2 pressure of the supply of pressurized breathable gas over an operating pressure range of about 4-25 gf/cm^2 .

35. A mask for delivering breathable gas to a patient as in claim 34, wherein the force F_c is maintained within a range of about 27 – 61 grams per gf/cm^2 pressure of 25 the supply of pressurized breathable gas.

36. A mask for delivering breathable gas to a patient as in claim 35, wherein the force F_c is maintained within a range of about 40 – 61 grams per gf/cm^2 pressure of the supply of pressurized breathable gas.

37. A mask for delivering breathable gas to a patient as in claim 36, wherein a total force of the mask on the face F_m is maintained within a range of about 35-88 grams per gf/cm^2 pressure of the supply of pressurized breathable gas over the operating pressure range of the mask.

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38. A mask for delivering breathable gas to a patient as in claim 37, wherein the force F_m is maintained within a range of about 40-88 grams per gf/cm^2 pressure of the supply of pressurized breathable gas.

10 39. A mask for delivering breathable gas to a patient as in claim 38, wherein the force F_m is maintained within a range of about 50-88 grams per gf/cm^2 pressure of the supply of pressurized breathable gas.

15 40. A mask for delivering breathable gas to a patient as in claim 39, wherein the expansion and contraction of the gusset portion permits a seal to be maintained between the cushion and the user's face within a range of about plus and minus 8 degrees angular displacement of the mask with respect to the user's face.

20 41. A breathable gas mask arrangement as in claim 34, wherein the gusset portion includes a single gusset having a flexible sidewall with a generally triangular cross-section when not exposed to the supply of pressurized breathable gas that balloons to a generally rounded cross-section when exposed to the supply of pressurized breathable gas.

25 42. A breathable gas mask arrangement as in claim 34, wherein the gusset portion includes a sidewall having a thickened cross-section at a base of the sidewall.

43. A breathable gas mask arrangement as in claim 42, wherein the thickened portion has a generally uniform thickness.

44. A breathable gas mask arrangement as in claim 42, wherein the gusset portion includes a sidewall having a cross-sectional thickness tapering from a thickened base portion to a thinner portion.

5 45. A breathable gas mask arrangement as in claim 34, and further including a generally rigid backstop attached to the mask shell for contacting a first sidewall portion of the gusset portion to limit movement of the first sidewall portion.

10 46. A breathable gas mask arrangement as in claim 45, wherein the generally rigid backstop extends around substantially an entire periphery of the gusset portion.

47. A breathable gas mask arrangement, comprising:

a mask shell having a portion adapted to receive a supply of pressurized breathable gas and a user side;

15 a gusset portion having a first side attached to the user side of the shell and having a second side;

a cushion having a first portion constructed and arranged to attach to the second side of the gusset portion and a second portion constructed and arranged to contact a user's face in use and provide a seal between the mask arrangement and the

20 user's face; and

a headgear constructed and arranged to attach the mask shell to the user;

wherein, the gusset portion is constructed and arranged such that it can expand and contract to alter a distance between the mask shell and the cushion, an interior of the gusset portion being exposed to the supply of pressurized breathable gas and 25 having a projected area on the user's face A_g which is greater than an area A_c of contact of the cushion with the user's face such that the supply of pressurized breathable gas acting on the area A_g provides a component of a contact force F_c of the cushion on the user's face, and a ratio of A_g/A_c is greater than 1.00, a change in total force of the mask on the face F_m being generally directly proportional at a given 30 operating pressure to a displacement of the mask shell toward the user's face from an initial seal position within a range of such mask shell displacement of about 6-25 mm.

48. A breathable gas mask arrangement as in claim 47, wherein the mask shell displacement is in a range of about 10-20 mm.

49. A breathable gas mask arrangement as in claim 48, wherein the ratio of A_g/A_c 5 is in a range of 1.50 – 4.00.

50. A breathable gas mask arrangement as in claim 49, wherein the gusset portion includes a single gusset having a flexible sidewall with a generally triangular cross-section when not exposed to the supply of pressurized breathable gas that balloons to a 10 generally rounded cross-section when exposed to the supply of pressurized breathable gas.

51. An apparatus for disposition between a mask shell and a face-contacting cushion of a breathable gas mask arrangement adapted to receive a supply of 15 pressurized breathable gas, comprising:

a gusset portion having a first side attachable to a user side of the mask shell and a second side attachable to the cushion;

wherein, the gusset portion is constructed and arranged such that it can expand and contract to alter a distance between the mask shell and the cushion, an interior of 20 the gusset portion being exposed to the supply of pressurized breathable gas and having a projected area on the user's face A_g which is greater than an area A_c of contact of the cushion with the user's face such that the supply of pressurized breathable gas acting on the area A_g provides a component of a contact force F_c of the cushion on the user's face, and a ratio of A_g/A_c is at least 1.30.

25

52. An apparatus as in claim 51, wherein the ratio of A_g/A_c is in a range of 1.50 to 5.00.

53. An apparatus as in claim 52, wherein the ratio of A_g/A_c is in a range of 2.00 to 30 4.00.

54. An apparatus as in claim 53, wherein the ratio of A_g/A_c is in a range of 2.25 to 3.50.

55. A breathable gas mask arrangement as in claim 53, wherein the gusset portion includes a single gusset having a flexible sidewall with a generally triangular cross-section when not exposed to the supply of pressurized breathable gas that balloons to a generally rounded cross-section when exposed to the supply of pressurized breathable gas.

10 56. A cushion assembly for attachment to a mask shell of a breathable gas mask arrangement adapted to receive a supply of pressurized breathable gas, comprising: a gusset portion having a first side attachable to a user side of the mask shell and having a second side;

15 a cushion having a first portion attached to the second side of the gusset portion and a second portion constructed and arranged to contact a user's face in use and provide a seal between the mask arrangement and the user's face; and

20 wherein, the gusset portion is constructed and arranged such that it can expand and contract to alter a distance between the mask shell and the cushion, an interior of the gusset portion being exposed to the supply of pressurized breathable gas and having a projected area on the user's face A_g which is greater than an area A_c of contact of the cushion with the user's face such that the supply of pressurized breathable gas acting on the area A_g provides a component of a contact force F_c of the cushion on the user's face, and a ratio of A_g/A_c is at least 1.30.

25 57. A cushion assembly as in claim 56, wherein the ratio of A_g/A_c is in a range of 1.50 to 5.00.

58. A cushion assembly as in claim 57, wherein the ratio of A_g/A_c is in a range of 2.00 to 4.00.

30

59. A cushion assembly as in claim 58, wherein the ratio of A_g/A_c is in a range of 2.25 to 3.50.

60. A breathable gas mask arrangement as in claim 58, wherein the gusset portion includes a single gusset having a flexible sidewall with a generally triangular cross-section when not exposed to the supply of pressurized breathable gas that balloons to a generally rounded cross-section when exposed to the supply of pressurized breathable gas.

61. A mask assembly for supplying pressurized breathable gas to a user, comprising:

10 a mask shell having a portion adapted to receive the pressurized breathable gas;

15 a cushion having a portion for contacting a user's face in use and providing a seal between the mask assembly and the user's face;

20 a suspension mechanism attached between the mask shell and the cushion; and a headgear for attaching the mask shell to the user;

25 wherein, the suspension mechanism is constructed and arranged such that it can expand and contract to alter a distance between the mask shell and the cushion, an interior of the suspension mechanism being exposed to the pressurized breathable gas and having a projected area on the user's face A_g which is greater than an area A_c of contact of the cushion with the user's face such that the pressurized breathable gas acting on the area A_g provides a component of a contact force F_c of the cushion on the user's face, and a ratio of A_g/A_c is at least 1.30.

62. A mask assembly as in claim 61, wherein the ratio of A_g/A_c is in a range of 25 1.50 to 5.00.

63. A mask assembly as in claim 62, wherein the ratio of A_g/A_c is in a range of 2.00 to 4.00.

30 64. A mask assembly as in claim 63, wherein the ratio of A_g/A_c is in a range of 2.25 to 3.50.

65. A breathable gas mask arrangement as in claim 63, wherein the gusset portion includes a single gusset having a flexible sidewall with a generally triangular cross-section when not exposed to the pressurized breathable gas that balloons to a generally rounded cross-section when exposed to the pressurized breathable gas.

5

66. A mask for delivering breathable gas to a patient, comprising:

a mask shell having a portion adapted to receive a supply of pressurized breathable gas and a user side;

10 having a second side;

a cushion having a first portion constructed and arranged to attach to the second side of the gusset portion and a second portion constructed and arranged to contact a user's face in use and provide a seal between the mask and the user's face; and

15 a headgear constructed and arranged to attach the mask shell to the user;

wherein, the gusset portion is constructed and arranged such that it can expand and contract within a range of displacement to alter a distance between the mask shell and the cushion, the gusset portion having a gusset area exposed to the supply of pressurized breathable gas in use such that the supply of pressurized breathable gas 20 acting on the gusset area provides a component of a contact force F_c of the cushion on the user's face, the force F_c being maintained within a range of about 0.3 – 4 grams per gf/cm^2 pressure of the supply of pressurized breathable gas per linear centimeter around a circumference of the cushion in contact with the user's face over an operating pressure range of about 4-25 gf/cm^2 .

25

67. A mask for delivering breathable gas to a patient as in claim 66, wherein the force F_c is maintained within a range of about 0.5 – 4 grams per gf/cm^2 pressure of the supply of pressurized breathable gas per linear centimeter around a circumference of the cushion in contact with the user's face.

30

68. A mask for delivering breathable gas to a patient as in claim 67, wherein the force F_c is maintained within a range of about 1 – 3 grams per gf/cm^2 pressure of the

supply of pressurized breathable gas per linear centimeter around a circumference of the cushion in contact with the user's face.

69. A mask for delivering breathable gas to a patient as in claim 68, wherein the
5 force F_c is maintained within a range of about 1.5 – 3 grams per gf/cm^2 pressure of the supply of pressurized breathable gas per linear centimeter around a circumference of the cushion in contact with the user's face.

70. A mask for delivering breathable gas to a patient as in claim 69, wherein a
10 total force of the mask on the face F_m is maintained within a range of about 35-88 grams per gf/cm^2 pressure of the supply of pressurized breathable gas over the operating pressure range of the mask.

71. A mask for delivering breathable gas to a patient as in claim 70, wherein the
15 force F_m is maintained within a range of about 40-88 grams per gf/cm^2 pressure of the supply of pressurized breathable gas.

72. A mask for delivering breathable gas to a patient as in claim 71, wherein the
force F_m is maintained within a range of about 50-88 grams per gf/cm^2 pressure of the
20 supply of pressurized breathable gas.

73. A mask for delivering breathable gas to a patient as in claim 72, wherein the expansion and contraction of the gusset portion permits a seal to be maintained between the cushion and the user's face within a range of about plus and minus 8
25 degrees angular displacement of the mask with respect to the user's face.

74. A breathable gas mask arrangement as in claim 72, wherein the gusset portion includes a single gusset having a flexible sidewall with a generally triangular cross-section when not exposed to the supply of pressurized breathable gas that balloons to a
30 generally rounded cross-section when exposed to the supply of pressurized breathable gas.

75. A mask assembly attachable to a user for receiving and supplying pressurized air to the user, comprising:

- a cushion for contacting a user's face; and
- a suspension mechanism axially movably supporting the cushion and exposed to the pressurized air to provide a first axial spring force to the cushion proportional to a pressure of the air, the first axial spring force being at least 30% greater than a second axial spring force on the cushion due to the pressurized air acting directly on the cushion.

10 76. A mask assembly as in claim 75, wherein the first axial spring force is between 200% and 400% greater than the second axial spring force.

77. A mask assembly as in claim 76, wherein the suspension mechanism includes at least one gusset having a flexible sidewall with a generally triangular cross-section when not exposed to the pressurized air that balloons to a generally rounded cross-section when exposed to the pressurized air.

15 78. A mask assembly attachable to a user for receiving and supplying pressurized air to the user, comprising:

- 20 a mask shell;
- a cushion for contacting a user's face and having a first projected area on the user's face; and
- a suspension mechanism attached to the mask shell axially movably supporting the cushion and having a second projected area on the user's face greater than the first projected area on the face by at least 30%.

25 79. A mask assembly as in claim 78, wherein the second projected area is between 200% and 400% greater than the first projected area.

30 80. A mask assembly as in claim 79, wherein the suspension mechanism includes at least one gusset having a flexible sidewall with a generally triangular cross-section

when not exposed to the pressurized air that balloons to a generally rounded cross-section when exposed to the pressurized air.

81. A breathable gas mask arrangement, comprising:

- 5 a mask shell having a portion adapted to receive a supply of pressurized breathable gas, and a cylinder portion axially extending on a user side;
- 10 a gusset portion having a first side in the form of a piston axially slideably engaged with the cylinder portion of the mask shell and a second side;
- 15 a cushion having a first portion constructed and arranged to attach to the second side of the gusset portion and a second portion constructed and arranged to contact a user's face in use and provide a seal between the mask arrangement and the user's face; and
- 20 a headgear constructed and arranged to attach the mask shell to the user; wherein, the piston can axially slide in the cylinder portion of the mask shell to alter a distance between the mask shell and the cushion, a surface of the piston being exposed to the supply of pressurized breathable gas and having a projected area on the user's face A_g which is greater than an area A_c of contact of the cushion with the user's face such that the supply of pressurized breathable gas acting on the area A_g provides a component of a contact force F_c of the cushion on the user's face, and a ratio of A_g/A_c is greater than 1.00.

82. A breathable gas mask arrangement as in claim 81, and further including a spring engaged between the mask shell and the piston to apply a retracting force between the mask shell and the piston.

- 25 83. A breathable gas mask arrangement as in claim 82, wherein the mask shell includes a stop portion for engaging the piston to limit axial movement of the piston.

- 30 84. A breathable gas mask arrangement as in claim 83, wherein the ratio of A_g/A_c is in a range of 1.50 – 4.00.

85. A breathable gas mask arrangement as in claim 81, wherein the ratio of A_g/A_c is in a range of 2.00 – 4.00.

86. A breathable gas mask arrangement, comprising:

5 a mask shell having a portion adapted to receive a supply of pressurized breathable gas and a user side;

a gusset portion having a first side attached to the user side of the shell and having a second side;

10 a cushion having a first portion constructed and arranged to attach to the second side of the gusset portion and a second portion constructed and arranged to contact a user's face in use and provide a seal between the mask arrangement and the user's face; and

a headgear constructed and arranged to attach the mask shell to the user;

15 wherein, the gusset portion is constructed and arranged such that it can expand and contract to alter a distance between the mask shell and the cushion, an interior of the gusset portion being exposed to the supply of pressurized breathable gas and having a projected area on the user's face A_g which is greater than an area A_c of contact of the cushion with the user's face such that the supply of pressurized breathable gas acting on the area A_g provides a component of a contact force F_c of the 20 cushion on the user's face, and a ratio of A_g/A_c is greater than 1.00, the gusset portion including a sidewall having a thickened cross-section at a base of the sidewall.

87. A breathable gas mask arrangement as in claim 86, wherein the thickened portion has a generally uniform thickness.

25

88. A breathable gas mask arrangement as in claim 87, wherein the ratio of A_g/A_c is in a range of 1.50-4.00.

30 89. A breathable gas mask arrangement as in claim 86, wherein the gusset portion includes a sidewall having a cross-sectional thickness tapering from a thickened base portion to a thinner portion.

90. A breathable gas mask arrangement as in claim 89, wherein the ratio of A_g/A_c is in a range of 1.50 – 4.00.

91. A breathable gas mask arrangement, comprising:

5 a mask shell having a portion adapted to receive a supply of pressurized breathable gas and a user side;

10 a gusset portion having a first side attached to the user side of the shell and having a second side;

15 a cushion having a first portion constructed and arranged to attach to the second side of the gusset portion and a second portion constructed and arranged to contact a user's face in use and provide a seal between the mask arrangement and the user's face;

20 a headgear constructed and arranged to attach the mask shell to the user; and a generally rigid backstop attached to the mask shell for contacting a first sidewall portion of the gusset portion to limit movement of the first sidewall portion; wherein, the gusset portion is constructed and arranged such that it can expand and contract to alter a distance between the mask shell and the cushion, an interior of the gusset portion being exposed to the supply of pressurized breathable gas and having a projected area on the user's face A_g which is greater than an area A_c of contact of the cushion with the user's face such that the supply of pressurized breathable gas acting on the area A_g provides a component of a contact force F_c of the cushion on the user's face, and a ratio of A_g/A_c is greater than 1.00.

25 92. A breathable gas mask arrangement as in claim 91, wherein the generally rigid backstop extends around substantially an entire periphery of the gusset portion.

30 93. A breathable gas mask arrangement as in claim 92, and further including a generally rigid second backstop attached to the mask shell for contacting a second sidewall portion of the gusset portion to limit movement of the second sidewall portion.

94. A breathable gas mask arrangement as in claim 93, wherein at least one of the backstop and the second backstop are indirectly attached to the mask shell.

95. A breathable gas mask arrangement as in claim 92, wherein the ratio of A_g/A_c 5 is in a range of 1.50 – 4.00.

96. A breathable gas mask arrangement as in claim 91, wherein the ratio of A_g/A_c is in a range of 2.00 – 4.00.

10 97. A breathable gas mask arrangement, comprising:
a mask shell having a portion adapted to receive a first supply of pressurized
breathable gas and a user side;
a gusset portion having a first side attached to the user side of the shell and
having a second side;
15 a cushion having a first portion constructed and arranged to attach to the
second side of the gusset portion and a second portion constructed and arranged to
contact a user's face in use and provide a seal between the mask arrangement and the
user's face; and
a headgear constructed and arranged to attach the mask arrangement to the
20 user;
wherein, the gusset portion is constructed and arranged such that it can expand
and contract to alter a distance between the mask shell and the cushion, the gusset
portion having a flexible sidewall with a cross-section enclosing a gusset chamber
having an interior volume separated from an interior of the mask shell, the sidewall
25 having at least one port connecting the gusset chamber to a second supply of
pressurized gas.

98. A breathable gas mask arrangement as in claim 97, wherein the pressure of the
second supply of pressurized gas is maintained at a different pressure than the
30 pressure of the first supply of pressurized breathable gas during at least a portion of a
treatment therapy.

99. A breathable gas mask arrangement as in claim 98, wherein the pressure of the second supply of pressurized gas is controlled in relation to the pressure of the first supply of pressurized breathable gas during at least a portion of a treatment therapy.

5 100. A breathable gas mask arrangement as in claim 98, wherein the pressure of the second supply of pressurized gas is controlled independently of the pressure of the first supply of pressurized breathable gas during at least a portion of a treatment therapy.

10 101. A breathable gas mask arrangement as in claim 97, wherein the gusset chamber has a generally circular cross-section.

102. A breathable gas mask arrangement as in claim 97, wherein the gusset chamber has

15 a generally diamond shaped cross-section when the mask is not in use that balloons to a generally circular cross-section when the gusset chamber is connected to the second supply of pressurized gas.

103. A breathable gas mask arrangement as in claim 97, wherein the mask shell includes a port therethrough integrally molded with the mask shell and interconnecting the sidewall port to the second supply of pressurized gas.

104. A mask cushion for sealingly connecting a breathing mask to a wearer's face, the cushion comprising:

25 a sidewall having an axially outer edge;
a flexible membrane attached to the sidewall, the membrane having a face contacting portion extending axially to a position beyond the axially outer edge of the sidewall and constructed and arranged to move axially between the extended position and a retracted position where the axially outer edge of the sidewall contacts the

30 wearer's face to limit further axial movement of the flexible membrane.

105. A mask cushion as in claim 104, wherein the axial movement of the face-contacting portion of the flexible membrane is substantially provided by the flexibility of the flexible membrane.

5 106. A mask cushion as in claim 105, wherein the flexible membrane is attached to the sidewall at a position axially inward from the axially outer edge and a portion of the flexible membrane extends axially outwardly alongside a portion of the sidewall.

10 107. A mask cushion as in claim 106, wherein the sidewall is at least partially hollow to increase flexibility of the sidewall.

108. A mask cushion as in claim 107, wherein the sidewall is at least partially hollow between the attachment position and the axially outer edge.

15 109. A mask cushion as in claim 104, and further comprising a flexible connecting member connecting the flexible membrane to the sidewall, the flexible connecting member allowing relative axial movement between the flexible membrane and the sidewall.

20 110. A mask cushion as in claim 109, wherein the flexible connecting member has a convoluted cross-section.

111. A mask cushion as in claim 109, wherein the flexible connecting member is attached to the sidewall at a position axially inward from the axially outer edge and a portion of the flexible membrane extends axially outwardly alongside a portion of the sidewall.

25 112. A mask cushion as in claim 111, wherein the flexible connecting member has a convoluted cross-section.

30 113. A mask cushion as in claim 111, wherein the sidewall is at least partially hollow to increase flexibility of the sidewall.

114. A mask cushion as in claim 113, wherein the sidewall is at least partially hollow between the attachment position and the axially outer edge.
- 5 115. A mask cushion as in claim 109, wherein the sidewall is at least partially hollow to increase flexibility of the sidewall.
116. A mask cushion as in claim 115, wherein the sidewall is at least partially hollow between the attachment position and the axially outer edge.
- 10 117. A mask cushion as in claim 104, wherein the sidewall is at least partially hollow to increase flexibility of the sidewall.
118. A mask cushion as in claim 117, wherein the sidewall is at least partially hollow between the attachment position and the axially outer edge.
- 15 119. A mask cushion as in claim 118, and further comprising:
 - a mask shell; and
 - a headgear for attaching the mask shell to the wearer's head;

20 wherein the cushion is attached to the mask shell for sealingly connecting the mask shell to the wearer's face.
120. A mask cushion as in claim 104, and further comprising:
 - a mask shell; and
 - a headgear for attaching the mask shell to the wearer's head;

25 wherein the cushion is attached to the mask shell for sealingly connecting the mask shell to the wearer's face.
121. A mask cushion as in claim 109, and further comprising:
 - 30 a mask shell; and
 - a headgear for attaching the mask shell to the wearer's head;

wherein the cushion is attached to the mask shell for sealingly connecting the mask shell to the wearer's face.

122. A mask cushion as in claim 104, wherein the flexible membrane is attached to
5 an interior of the sidewall and is in the shape of an inwardly curved rim.

123. A mask cushion as in claim 109, wherein the flexible membrane is attached to an interior of the sidewall and is in the shape of an inwardly curved rim.

10 124. A mask cushion as in claim 120, wherein the flexible membrane is attached to an interior of the sidewall and is in the shape of an inwardly curved rim.

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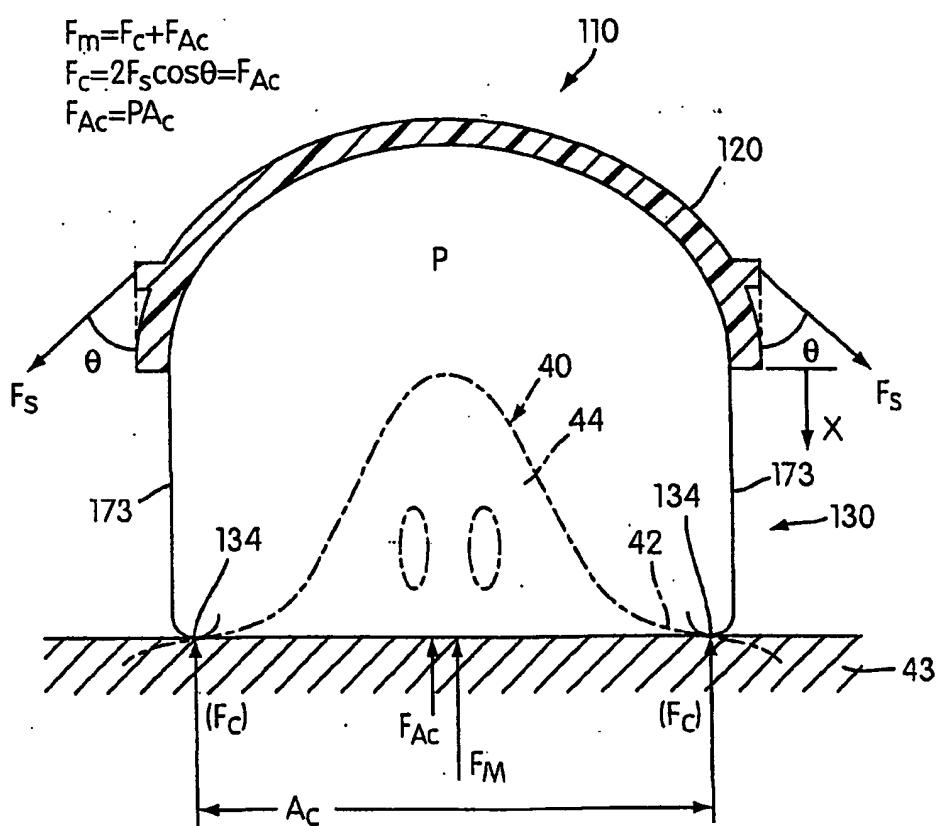
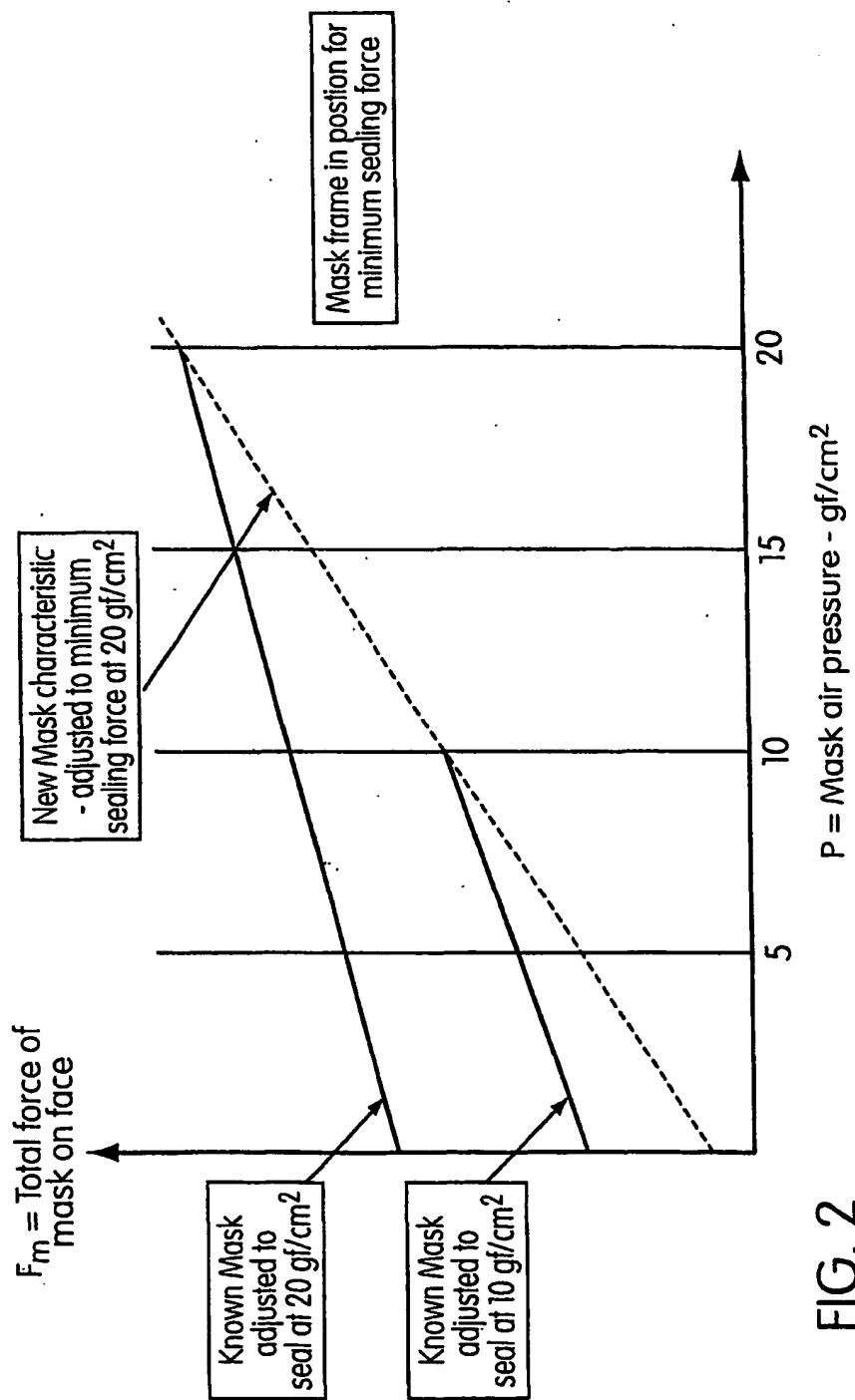
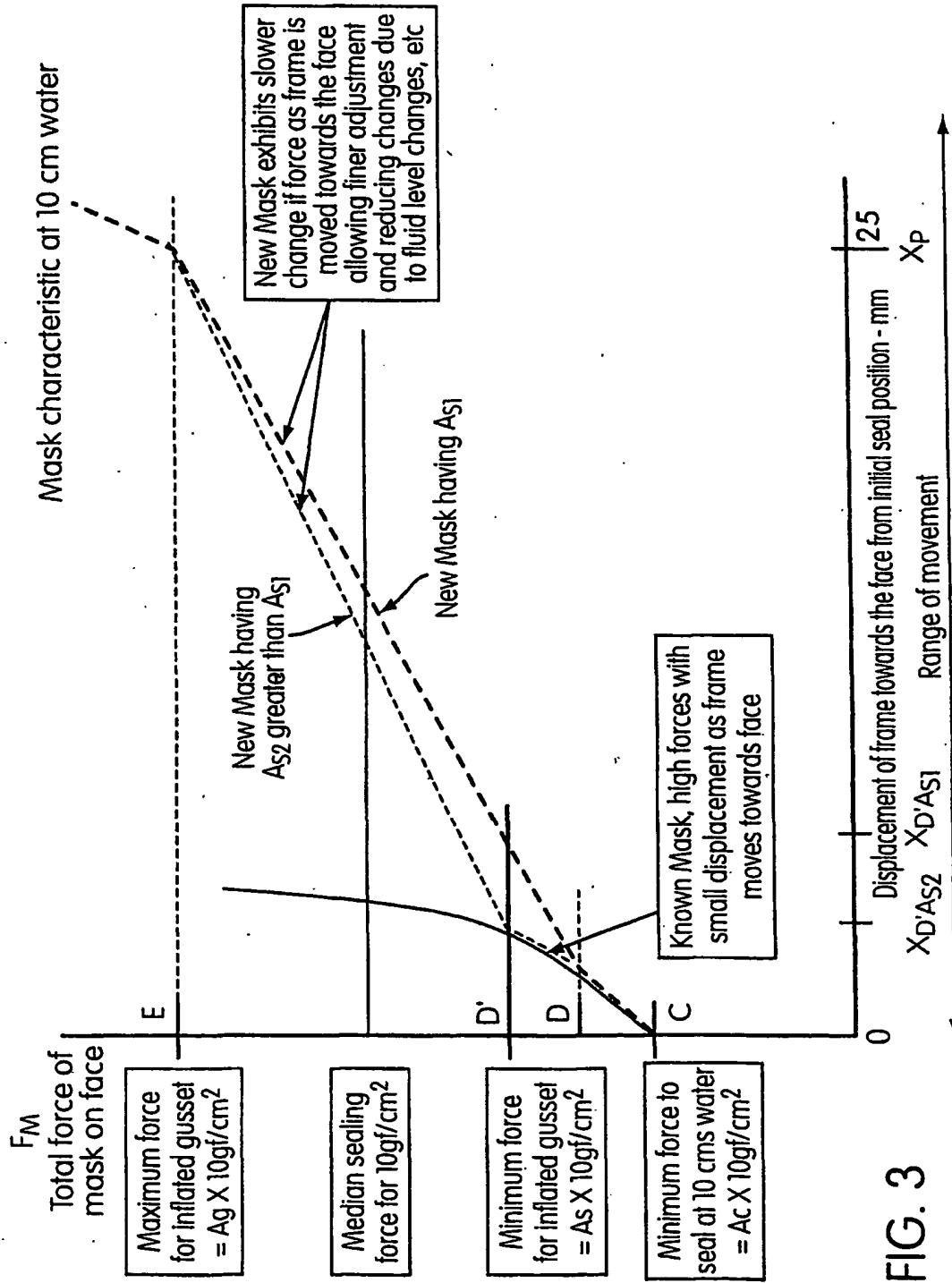
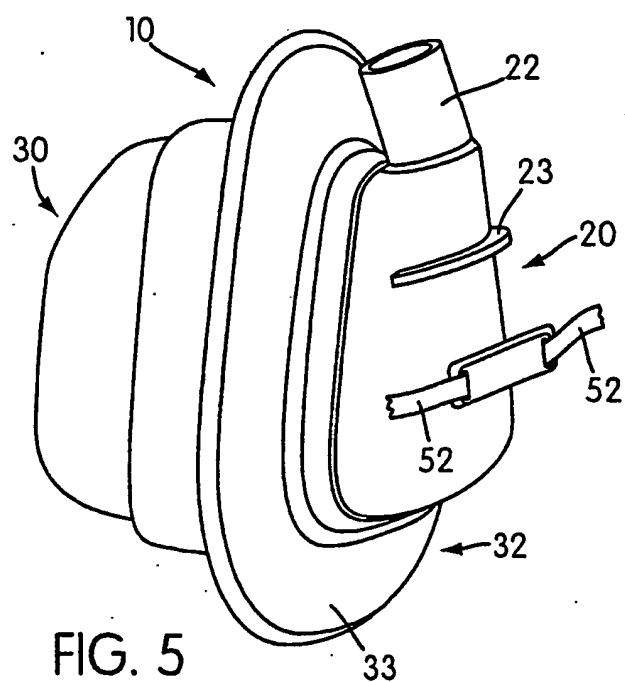
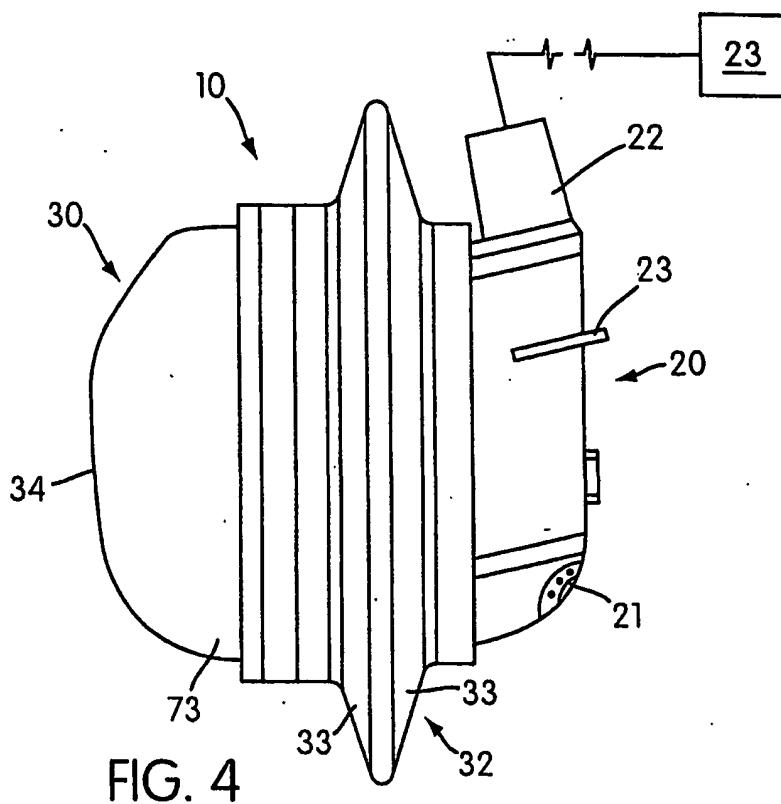


FIG. 1





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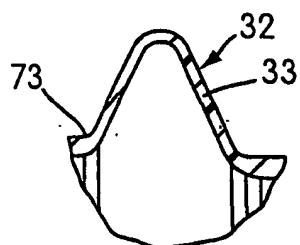


FIG. 6

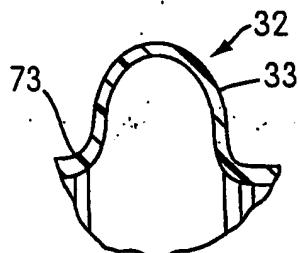


FIG. 7

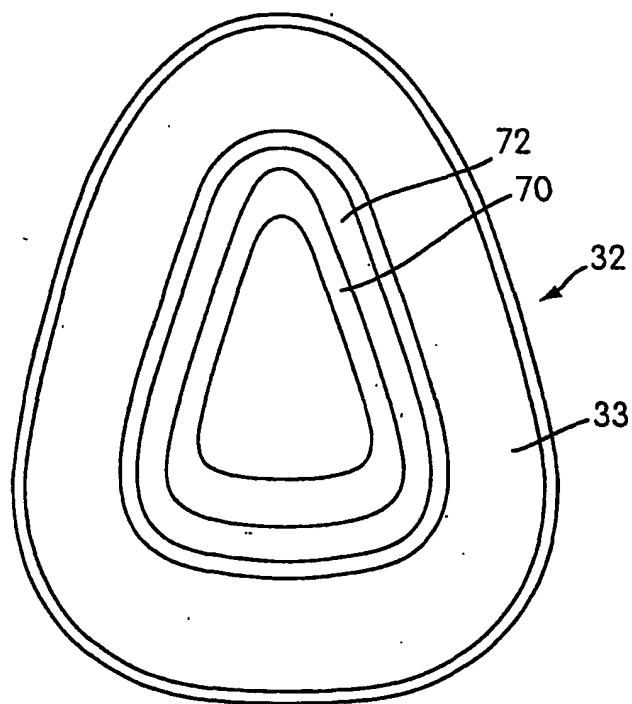


FIG. 8

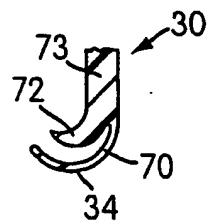


FIG. 9

$$F_M = P(A_g - kX) = 2F_s \cos\theta = F_c + F_{Ac}$$

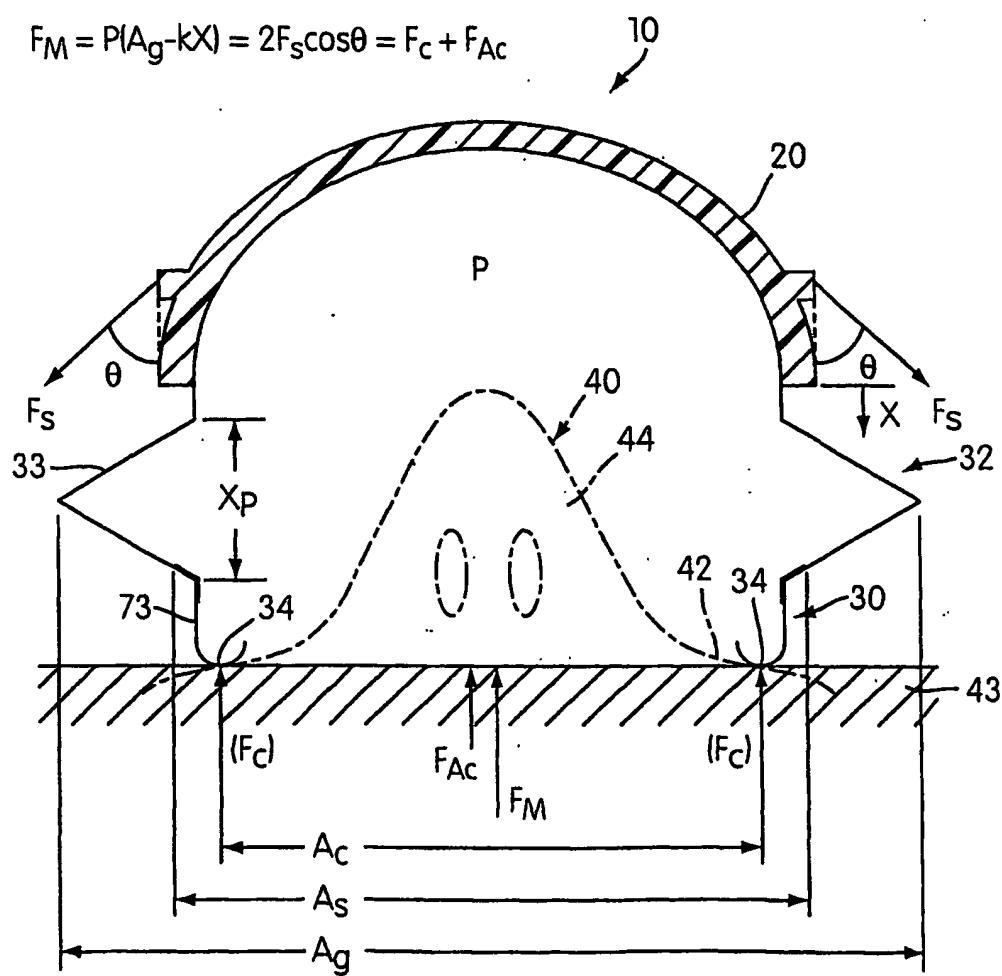


FIG. 10

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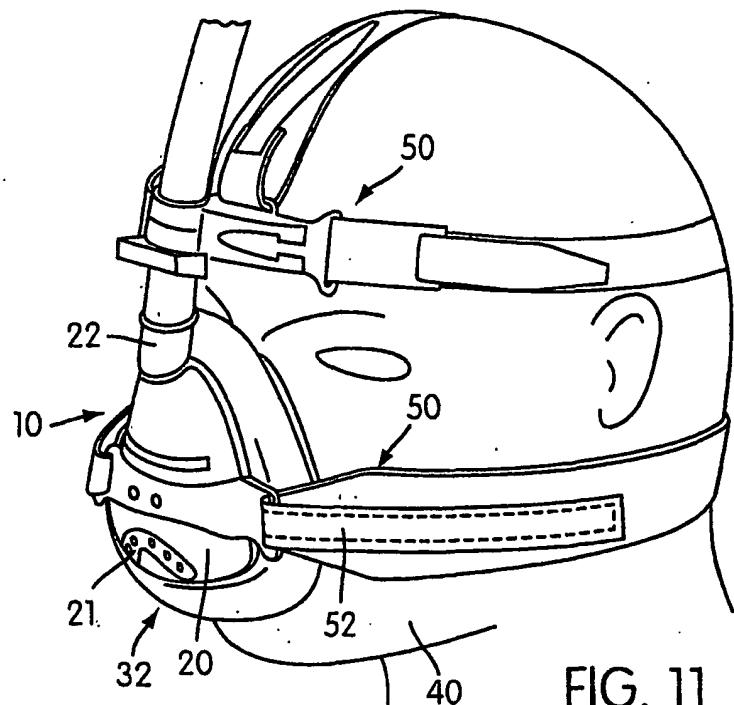


FIG. 11

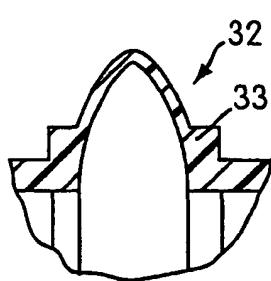


FIG. 12

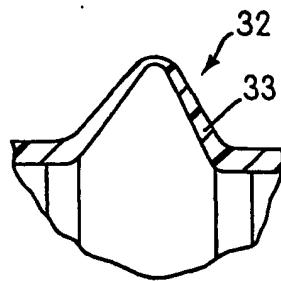


FIG. 14

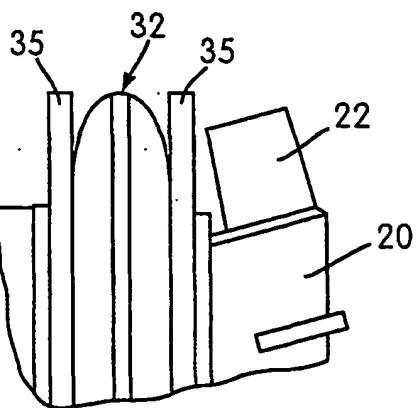


FIG. 13

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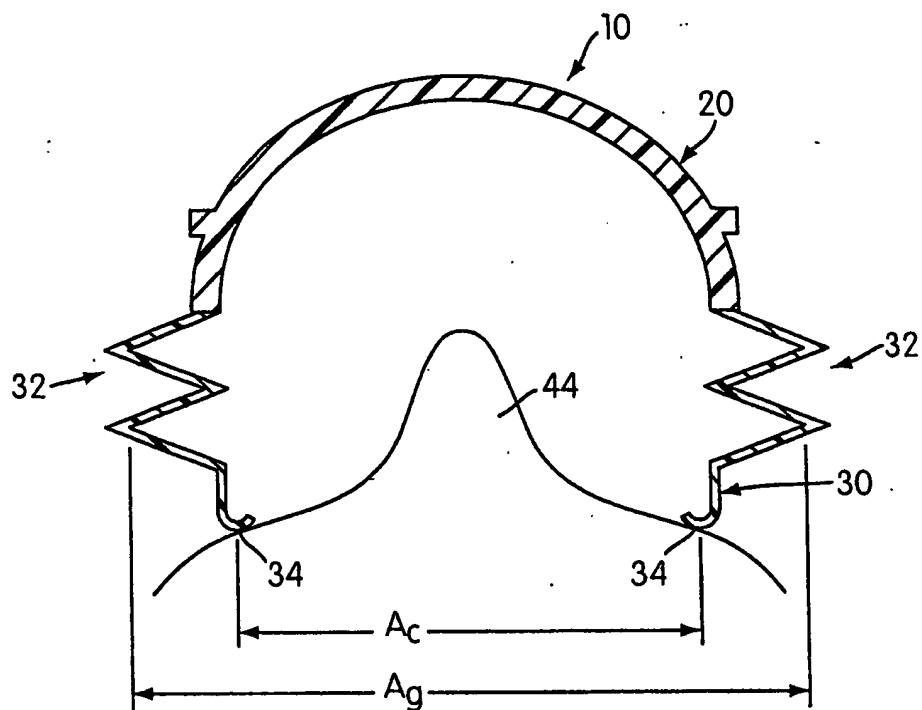


FIG. 15

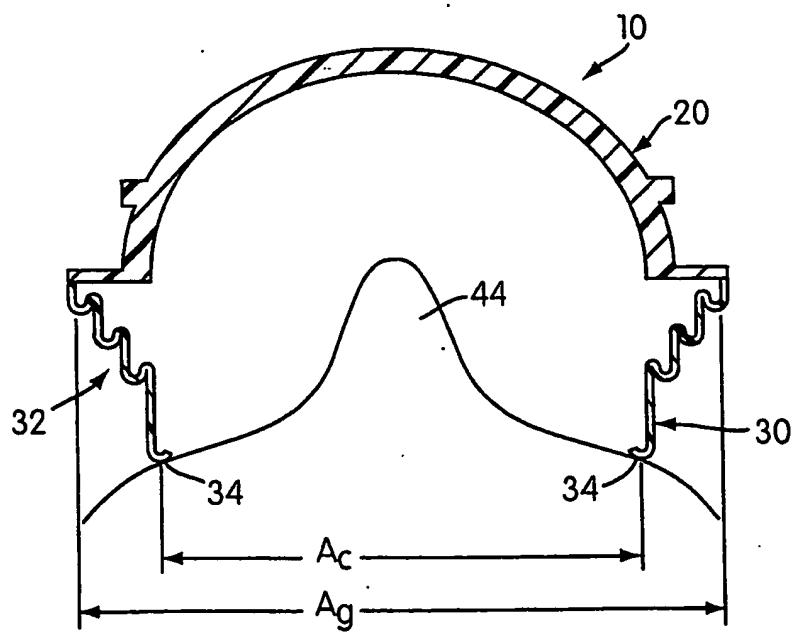


FIG. 16

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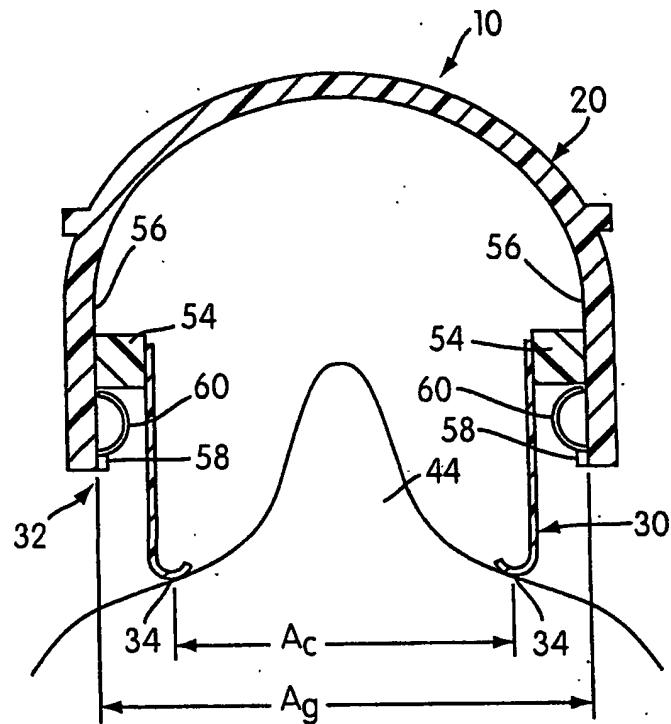


FIG. 17

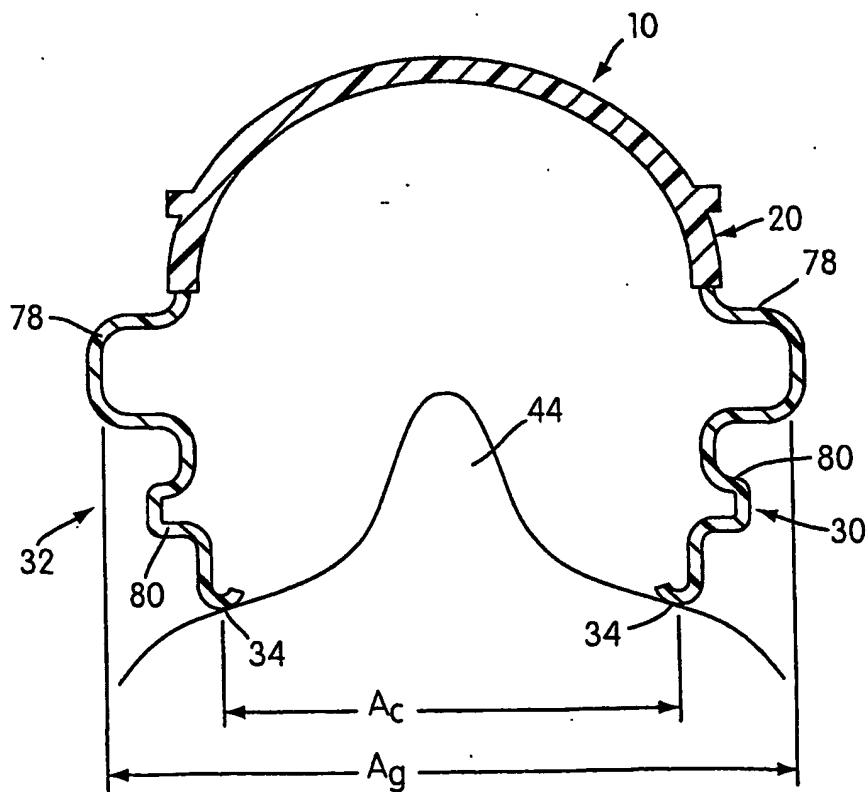


FIG. 18

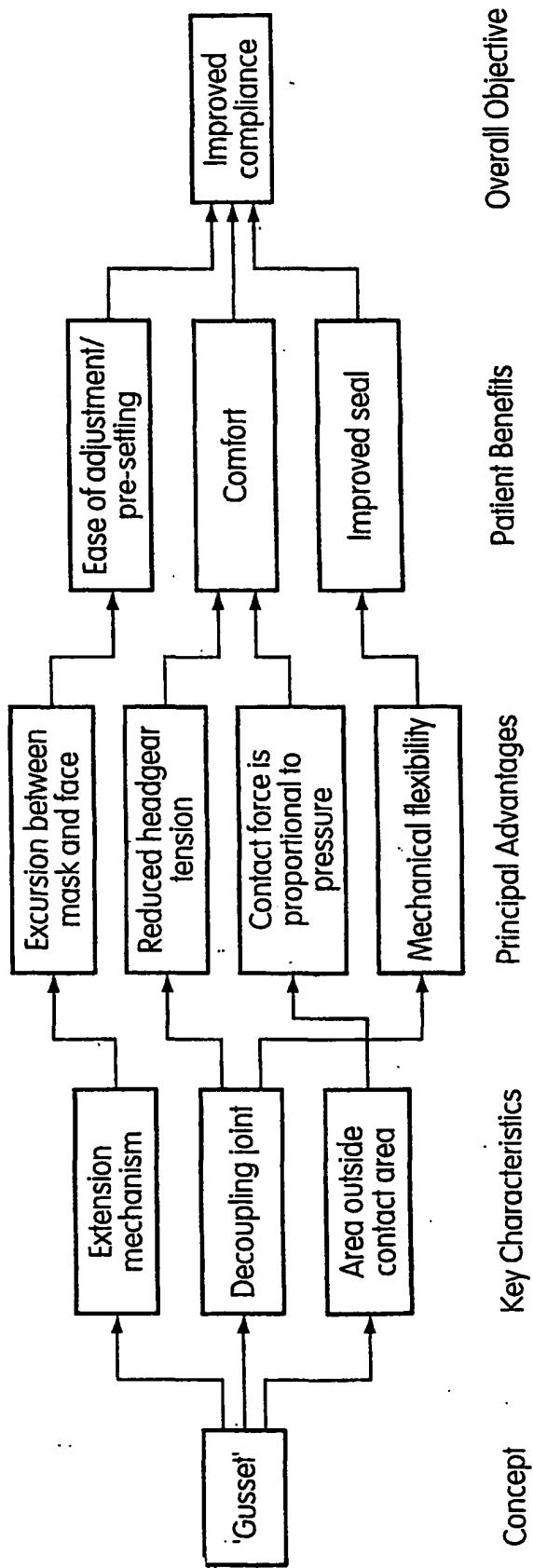


FIG. 19

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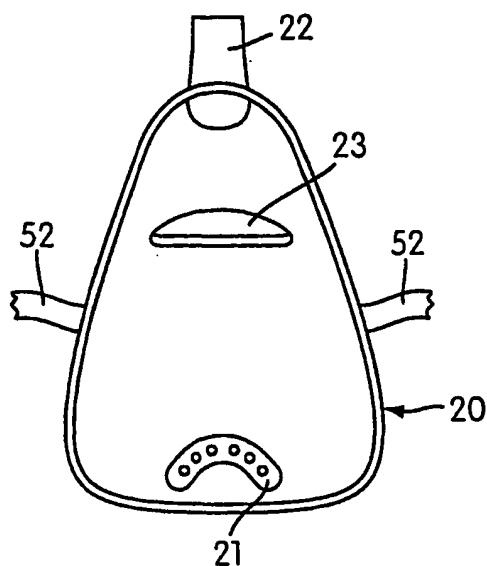


FIG. 20

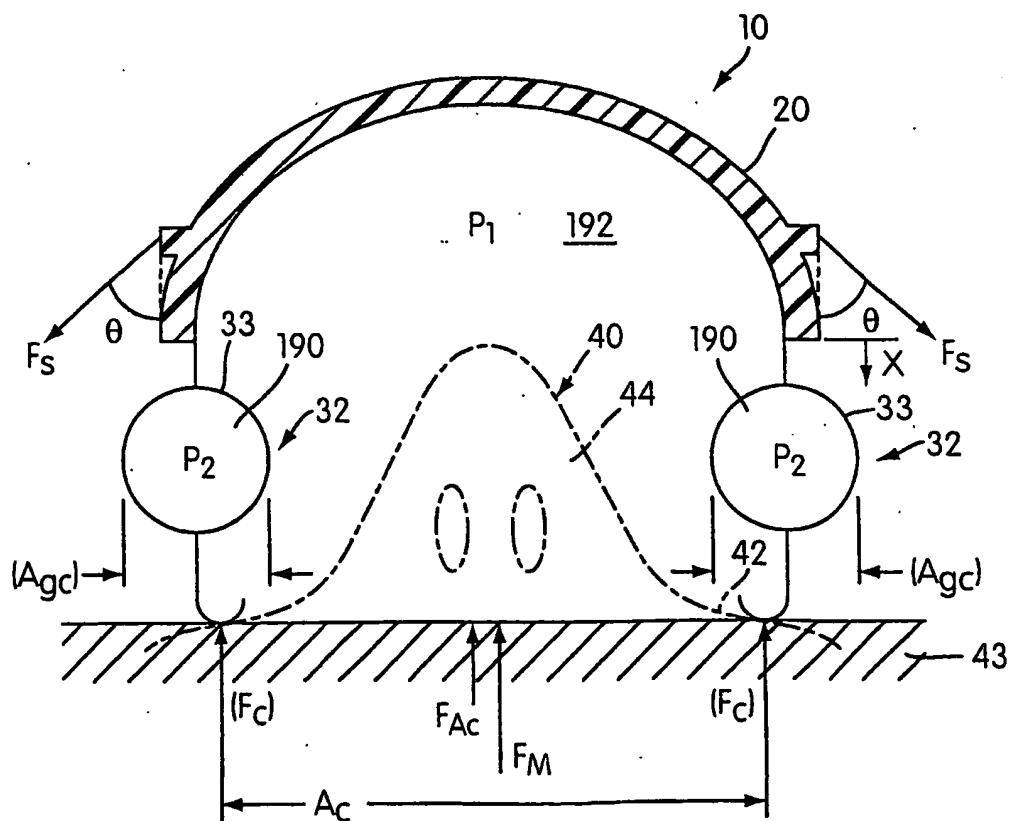


FIG. 21

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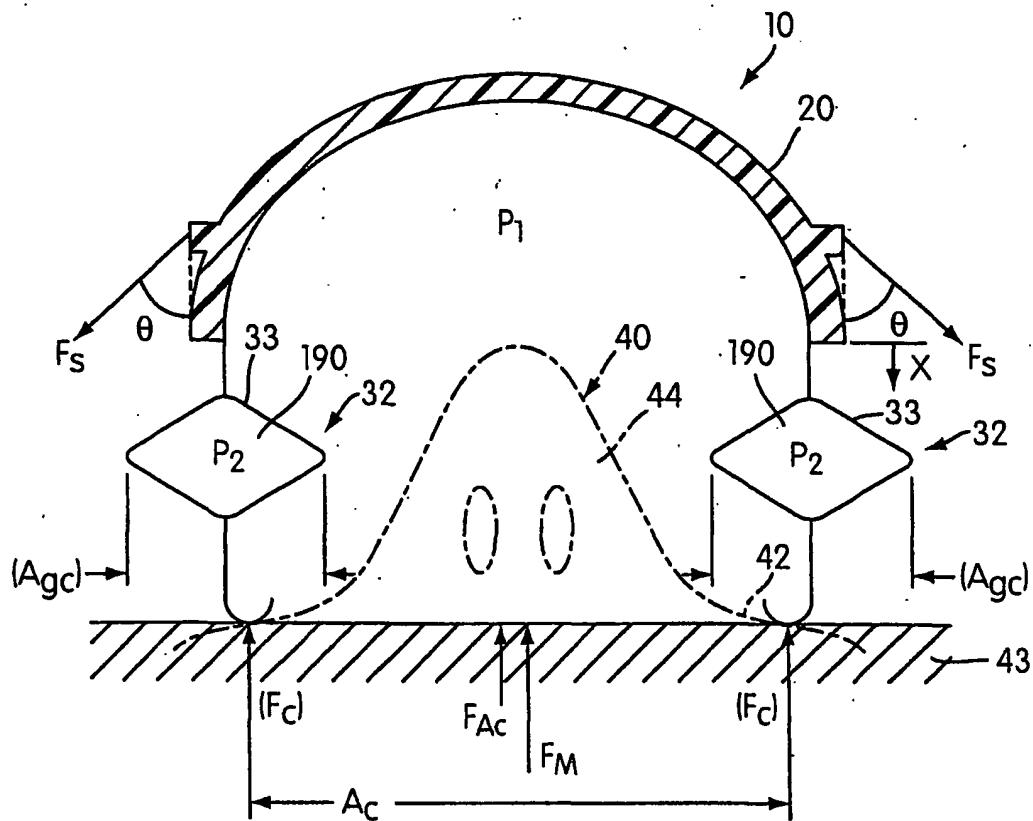


FIG. 22

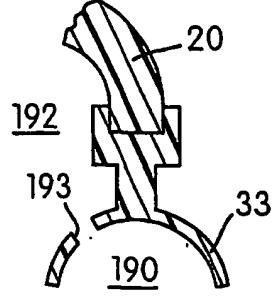


FIG. 23

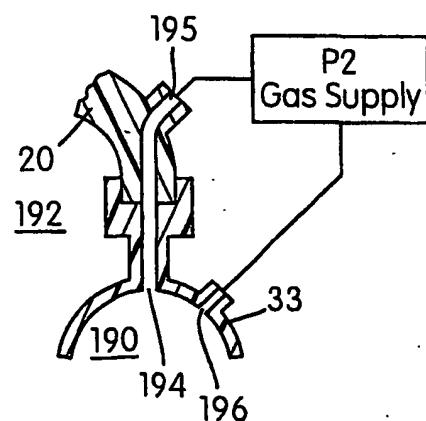


FIG. 24

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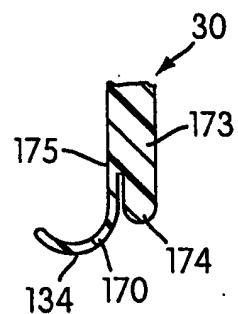


FIG. 25

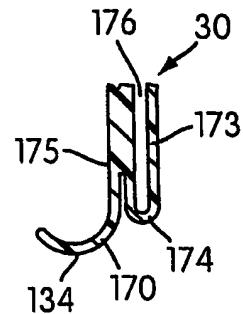


FIG. 26

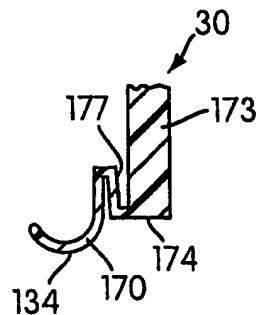


FIG. 27

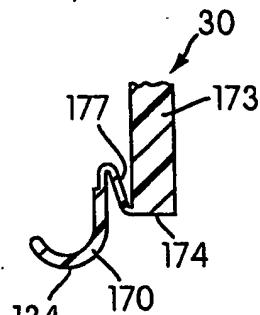


FIG. 28

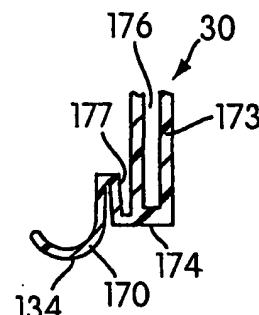


FIG. 29

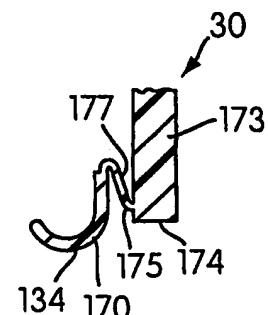
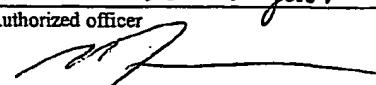


FIG. 30

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU01/00746

| | | |
|--|---|-----------------------|
| A. CLASSIFICATION OF SUBJECT MATTER | | |
| Int. Cl.?: A61M 16/06 A62B 18/08 | | |
| According to International Patent Classification (IPC) or to both national classification and IPC | | |
| B. FIELDS SEARCHED | | |
| Minimum documentation searched (classification system followed by classification symbols) SEE ELECTRONIC DATABASES CONSULTED | | |
| Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched AU IPC: A61M 16/06 A62B 18/08 | | |
| Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) DWPI JAPIO: mask gusset gasket apron skirt bellow accordion diaphragm expand contract extension extend A61M A62B A61H | | |
| C. DOCUMENTS CONSIDERED TO BE RELEVANT | | |
| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
| X | US 4069516 A (WATKINS) 24 January 1978 Entire document | 1-124 |
| X | EP 303090 B1 (SGE SOCIETA' GENERALE ELASTOMERI S.p.A.) 15 February 1989 Entire document | 1-124 |
| X | EP 853962 A2 (OCEAN REEF S.r.l) 22 July 1998 Column 4 line 42 to column 5 line 15 | 1-124 |
| <input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C <input checked="" type="checkbox"/> See patent family annex | | |
| * Special categories of cited documents: "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier application or patent but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed | | |
| Date of the actual completion of the international search <u>27 August 2001</u> | Date of mailing of the international search report <u>30 August 2001</u> | |
| Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaaustralia.gov.au Facsimile No. (02) 6285 3929 | Authorized officer  MATTHEW FORWARD Telephone No : (02) 6283 2606 | |

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU01/00746

| C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT | | |
|---|--|--------------------------|
| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
| X | JP 11-397 (TEJIN LTD) 6 January 1999 Figures | 34-46, 66-80, 104-124 |
| A | EP 334555 A2 (SABRE SAFETY LIMITED) 27 September 1989 Figure 1 | |

INTERNATIONAL SEARCH REPORT

| |
|--|
| International application No. PCT/AU01/00746 |
|--|

Box I Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos :
because they relate to subject matter not required to be searched by this Authority, namely:

2. Claims Nos :
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. Claims Nos :
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

Box II Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

See extra sheet

1. As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

The additional search fees were accompanied by the applicant's protest.
 No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU01/00746

Supplemental Box

(To be used when the space in any of Boxes I to VIII is not sufficient)

Continuation of Box No: II

The international application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept. In coming to this conclusion the International Searching Authority has found that there are different inventions as follows:

1. Claims 1 to 22 are characterised by a gusset portion on a gas/respiration mask that contacts the user's face in addition to a cushion seal. The gusset contacts at least 30% more of the user's face than the cushion. Claims 51 to 55 define the gusset only, claims 56 to 60 the cushion and gusset, claims 61 to 65 define the same concept but in a "mask for delivering breathable gas" and claims 78 to 80 define the same concept again but in a simplified format. It is considered that a gusset that contacts 30% more of the user's face than the cushion seal when a supply of gas is operating through a mask comprises a first "special technical feature".
2. Claims 23 to 33 are characterised by a gusset portion in addition to a cushion seal. When acted on by a gas supply in the mask, the gusset provides a component of the cushion contact force on the user's face in proportion to the supply of pressurised gas. The total force of the mask on the user's face must remain in the range of 35 to 108 g/gf/cm² pressure of the supply. It is considered that this requirement on the force acting on the user's face comprises a second "special technical feature".
3. Claims 34 to 46 have a gusset portion that provides a component of a cushion contact force on the user's face, in the range of 8-61 g/gf/cm² supply pressure over an operating pressure of 4-25gf/cm². The total force or contact area on the user's face is not defined. Claims 66 to 74 define a similar concept, but the cushion contact force component is in the range of 0.3-4 g/gf/cm². A gusset acting as defined when exposed to a gas supply pressure comprises a third special technical feature.
4. Claims 47 to 50 define yet another mask arrangement with a gusset characterised by having a contact area on the user's face at least equal to the contact area of the cushion seal and a total force of the mask acting on the face directly proportional to the displacement of the mask shell towards the user's face, within a displacement range of 6-25mm. Claims 81 to 85 define the gusset as a piston slideably engaged with the shell portion of the mask. This gusset has the contact area requirement, omits the displacement feature and includes a feature of the gusset providing a component of the cushion contact force on the user's face. Claims 86 to 90 define the same gusset operation requirements as claims 81 to 85, but with the gusset including a sidewall and a thickened cross-section its base. Claims 91 to 96 have the same gusset operation requirements and include a rigid backstop on the mask shell to contact a sidewall of the gusset and consequently limit movement of the gusset. A gusset that at least equals the cushion contact area on the user's face provides a fourth special technical feature.
5. Claims 97 to 103 define a breathable gas mask characterised by a gusset having a chamber, with a port connecting the chamber to a second pressurised gas supply. This gusset constitutes a fifth special technical feature.

Continued/

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU01/00746

Supplemental Box

(To be used when the space in any of Boxes I to VIII is not sufficient)

Continuation of Box No: II

6. Claims 104 to 124 define a mask cushion having a sidewall attached to an outer edge and a flexible membrane attached to the sidewall. The membrane has a face contacting portion extending beyond the axial outer edge of the cushion sidewall and is able to move between an extended and retracted position. Said axial outer edge limits further axial movement of the membrane when it contacts the user's face. This disposition of membrane and seal constitutes a sixth special technical feature.

These groups are linked by the concept of a gusset portion on a breathable gas mask. However this concept is disclosed by the documents cited in this Search Report and the claim set lacks unity "a posteriori".

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/AU01/00746

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

| Patent Document Cited in Search Report | | | Patent Family Member | |
|---|---------|----|----------------------|------------|
| US | 4069516 | NO | FAMILY | |
| EP | 303090 | CH | 671702 | DE 3870351 |
| EP | 853962 | IT | 970077 | US 6155253 |
| JP | 11-397 | NO | FAMILY | |
| EP | 334555 | GB | 2215615 | US 4886056 |

END OF ANNEX

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